EXHIBIT 4

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Trisha Tshudy *Plaintiff* v. Pennsylvania State University *Defendant*	Civil Action No. 22-cv-03336 Hon. Wendy Beetlestone

DECLARATION OF LAURA H. WILLIAMS

Laura H. Williams, of full age, hereby declares as follows:

1. I am the Associate Dean for Administration, Honor Code Administrator, and an Adjunct Professor of Law at Penn State Dickinson Law ("Dickinson Law").

2. I make this Declaration on the basis of personal knowledge and my review of materials kept by Dickinson Law in the regular and ordinary course of business.

3. As a result of my positions as Associate Dean for Administration and Honor Code Administrator, and involvement in some of the events at issue, I have knowledge of and am familiar with the events that give rise to the Complaint filed by Plaintiff, Trisha Tshudy ("Ms. Tshudy").

4. On or about December 31, 2021, Adjunct Professor, James M. Gould, alerted me to suspected plagiarism by Ms. Tshudy in connection with a final paper she submitted for the Fall 2021 course, Biotech, Pharmaceuticals and the Law. In his report to me, Professor Gould related a high degree of tracking with a Note published by Hannah-Alise Rogers entitled *Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v.*

Amphastar, 22 J. Intell. Prop. L. (2014) (the "Rogers Note"). A true and correct copy of Professor Gould's email report to me is attached hereto as **Exhibit A**.

5. Professor Gould also provided a copy of Ms. Tshudy's paper in which he highlighted several examples that appeared to be direct copies from the Rogers Note. See id. Professor Gould did not employ any kind of automated plagiarism checker in preparing his highlighted copy of Ms. Tshudy's paper. See id.

6. At all times material hereto, Dickinson Law had in place an Honor Code that set forth ethical rules, principles, and standards of academic integrity for its students in order to "safeguard and promote the ideals of honor and integrity by prohibiting lying, cheating, stealing, and other dishonorable conduct of an academic nature." A true and correct copy of the applicable Dickinson Law Honor Code is attached as **Exhibit B**.

7. The Dickinson Law Honor Code also sets forth the procedure for adjudicating alleged substantive violations of the Honor Code, including, but not limited to, plagiarism. Id.

8. Dickinson Law's Honor Code defines "plagiarism" as follows:

> Should be given its usual dictionary meanings: to steal and pass off (the ideas or words of another) as one's own; to use (a created production) without crediting the source or to commit literary theft, presenting as new and original an idea or product derived from an existing source. Plagiarism includes the copying or paraphrasing without acknowledgment of any material written or expressed by another person, and the submission of work written in whole or in substantial part by someone other than the student who submits the work as the student's own work. Plagiarism also includes the re-submission of work originally completed for another course and the giving or receiving of excessive assistance or making excessive use of the work of someone else in preparing an assignment, without faculty approval. What constitutes "excessive assistance" or "making excessive use of the work of someone else" is a matter for the course professor to decide and communicate in a timely manner to the students. Unless the course professor gives different instructions, "excessive assistance" should be construed with

> reference to the academic purpose of the assignment - to develop the student's research and writing skills and to evaluate his or her skills. A student may receive some counsel and suggestions from other people, e.g., another student, the course professor, so long as the paper is, in both pedagogical and literary senses, the work of the student.

Id. at Article 1.1(L).

9. The Biotech, Pharmaceuticals and the Law Course Policies also contains a section entitled Academic Integrity Statement which references the Honor Code and the expectations of students enrolled in the course. A true and correct copy of the Biotech, Pharmaceuticals and the Law Course Polices is hereto as **Exhibit C**.

10. On or about January 2, 2022, I initially utilized a plagiarism comparison program to compare Ms. Tshudy's paper with the Rogers Note, which demonstrated that 29% of Ms. Tshudy's paper represented content from the Rogers Note. A true and correct copy of this Comparison Report is hereto as **Exhibit D**.

11. On or about January 3, 2022, I proceeded to manually compare Ms. Tshudy's paper with the Rogers Note by highlighting the similarities between the two papers, which revealed even more content from the Rogers Note was contained in Ms. Tshudy's paper as compared to the original comparison report referenced above. A true and correct copy of Ms. Tshudy Paper with my highlighting is attached as **Exhibit E**. A true and correct copy of the Rogers Note with my highlighting is attached as **Exhibit F**.

12. On or about January 3, 2022, Professor Sabrina Sondhi, a member of the Dickinson Law Honor Committee, and myself informed Ms. Tshudy of an accusation of plagiarism regarding the paper by telephone. Following the call, I sent an email to Ms. Tshudy acknowledging the call

and sent the text of the Dickinson Law Honor Code. A true and correct copy of this email, dated January 3, 2022, is attached as **Exhibit G**.

13. On or about January 4, 2022, I notified Ms. Tshudy that based on my highlighted comparison of her paper to the Rogers Note (a comparison which I provided to Ms. Tshudy for review), her paper was in direct contravention of the Dickinson Law Honor Code. A true and correct copy of this email, dated January 4, 2022, is attached hereto as **Exhibit H**. I further notified Ms. Tshudy that if she elected not to make a Conscientious Admission per the Dickinson Law Honor Code, that I would recommend to the Honor Committee Chair that the matter proceed to a hearing. Id.

14. Ms. Tshudy elected to not make the above referenced Conscientious Admission.

15. I proceeded to report the suspected instance of plagiarism to the Chair of the Dickinson Law Honor Committee, and I provided the Chair with Professor Gould's initial report of the violation. The Chair determined that probable cause existed to believe the Honor Code has been violated. See **Exhibit B**, Article 5.2. Thereafter, steps were taken to hold an Honor Code Hearing, including assembling a Hearing Board. The Hearing Board consisted of three students, as well as two members of Dickinson Law's faculty, Professors William E. Butler and Megan Riesmeyer, all of whom, at the time, were members of Dickinson Law's Honor Committee. See **Exhibit B**, Article 5.3.

16. On January 6, 2022, the Honor Committee Chair issued a Notice of Honor Code Proceeding to Ms. Tshudy, which set a hearing date and time of January 14, 2022, 1:00 p.m. A true and correct copy of the Notice of Honor Code Proceeding, dated January 6, 2022, is attached hereto as **Exhibit I**.

17. As the Honor Code Administrator, I am charged with presenting a case against an Accused Student under the Dickinson Law Honor Code as the Presenter. See **Exhibit B**, at Articles 5.3 and 5.5.

18. On January 7 and 10, 2022, and per Chapter Three of the Dickinson Law Honor Code, entitled Rights of the Accused, I provided and otherwise identified evidence that would be used at the January 14, 2022 hearing to Ms. Tshudy. A true and correct copy of this email chain, dated January 7-10, 2022, is attached hereto as **Exhibit J**. See also, **Exhibit B**, at Article 3.1. I expressly notified Ms. Tshudy that "[a] side-by-side comparison of your paper and the Law Review Note, run through plagiarism software," would be utilized as evidence at the hearing. See id. In addition, I provided these materials to the Hearing Board members in advance of the Hearing as required by the Honor Code. True and correct copies of these emails as I sent to the Hearing Board are attached hereto as **Exhibits K and L**.

19. On January 12, 2022, I compared Ms. Tshudy's paper and the Rogers Note with an online plagiarism checker hosted at www.turnitin.com, which demonstrated similar content from the Rogers Note was contained in Ms. Tshudy's paper, as was already illustrated in my hand-highlighted versions. A true and correct copy of the Ms. Tshudy's paper compared by Turnitin is attached hereto as **Exhibit M**. A true and correct copy of the Rogers Note compared by Turnitin is attached hereto as **Exhibit N**. On January 13, 2022, I provided a copy of these comparisons to Ms. Tshudy and noted that they "may be easier to read than the hand-highlighted version I sent previously." A true and correct copy of my email to Ms. Tshudy providing a copy of these comparisons is attached as **Exhibit O**.

20. Prior to the hearing, Ms. Tshudy did not request an open hearing and further did not at any time challenge any potential Hearing Board Member for cause. See **Exhibit B**, at Article 3.1(B)-(C).

21. The Honor Code Hearing was held on January 14, 2022 and lasted over four and a half hours. Ms. Tshudy did not appear at the hearing with legal representation, as is expressly permitted by the Honor Code. See **Exhibit B**, at Chapter Three. During the hearing, the Board questioned Ms. Tshudy extensively, reviewed relevant documents (including the Turnitin and hand-highlighted comparisons), and heard testimony from Professor Gould about the gravity of the violation and the portions of the Rogers Note contained in Ms. Tshudy's paper, without citation to the Rogers Note. In accordance with Chapter Three of the Dickinson Law Honor Code, Ms. Tshudy attended the hearing where she testified, offered relevant evidence, was able to examine witnesses, including myself and Professor Gould, and made closing remarks. Ms. Tshudy attended the hearing with a witness, but ultimately declined to call this witness to testify on her behalf. A true and correct copy of the Hearing Board's Report, dated January 15, 2022, is attached as **Exhibit P**. See **Exhibit B**, at Article 3.2.

22. The Hearing Board found:

> Professor Gould became concerned about a possible violation of the Honor Code without having undertaken any exhaustive verification or using any automatic plagiarism checker. He found no reference to the Rogers Note in Ms. Tshudy's paper. Having contacted Associate Dean Jeffrey Dodge about the matter, who directed Professor Gould to alert Dean Williams, on 31 December 2021 Professor Gould notified Dean Williams by email of his concern.

Id., at pg. 1.

23. Following their post-hearing deliberations, the Honor Code Hearing Board unanimously concluded, on the basis of clear and persuasive evidence, that Ms. Tshudy had violated Article 2.1(F) of Dickinson Law's Honor Code and made the following factual findings:

> (a) Ms. Tshudy had drawn upon and sometimes copied verbatim the Note published by Rogers in 2014 when preparing her assignment for Professor Gould in violation of the course instructions and of the Honor Code; and
>
> (b) Ms. Tshudy was, at least disingenuous, and, at worst dishonest in explaining the similarities between the Rogers Note and her own paper.

Id. at p. 3.

24. In view of its findings, the Honor Code Hearing Board issued the following sanctions to Ms. Tshudy:

> (a) A written reprimand to be included in Ms. Tshudy's student record;
>
> (b) Denial of credit for the course, "Biotech, Pharmaceuticals and the Law" with an appropriate transcript entry;

Id. at p. 4.

25. The Hearing Board also recommended that:

> a) Ms. Tshudy schedule a meeting with Associate Dean Jeffrey Dodge to discuss mental health assistance; and,
>
> b) Ms. Tshudy schedule a meeting with Professor Titichia Jackson to receive counseling on academic success.

Id.

26. On January 16, 2022 the Hearing Board issued its Final Report to myself and Ms. Tshudy. A true and correct copy of an email issuing the Report to me is attached hereto as **Exhibit Q**.

27. The Dickinson Law Honor Code provides a right to appeal a decision of the Hearing Board to the Dean of Dickinson Law within seven (7) days of receipt of the report. See **Exhibit B**.

28. On January 16, 2022, I provided a copy of the final report of the Hearing Board to Danielle M. Conway, Dean and Donald J. Farage Professor of Law at Dickinson Law. See **Exhibit Q**.

29. Thereafter, I understand that Ms. Tshudy exercised her right to appeal to the Honor Code Hearing Board's decision to Dean Conway.

I understand that this Declaration is made subject to the penalties relating to unsworn falsification to authorities, 28 U.S.C. § 1746.

Dated: September 3, 2022

Laura H. Williams
Dean for Administration, Honor Code Administrator
and Adjunct Professor of Law

EXHIBIT A

Williams, Laura H

From: Gould, James M
Sent: Friday, December 31, 2021 12:50 AM
To: Williams, Laura H
Cc: Dodge, Jeffrey A
Subject: Possible Honor Code Violation
Attachments: Tshudy - Research Paper Final.docx; Tshudy - Research Paper Final - with highlighting.docx

Dear Laura,

As directed by Jeffrey Dodge (also copied on this email), I am forwarding the final paper submitted on December 17th by 2L student Trisha Tshudy for my course Biotech, Pharmaceuticals & the Law (Cert 997). In the course of grading Ms. Tshudy's paper, I became aware of the following Note published in 2014 in the Journal of Intellectual Property Law: Hannah-Alise Rogers, *Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar*, 22 J. Intell. Prop. L. 209 (2014); available at: https://digitalcommons.law.uga.edu/jipl/vol22/iss1/8. In reviewing this Note, I became concerned regarding a possible violation of the Honor Code due to the relatively high degree of tracking of the Note's content, including cited cases and numerous examples of actual passages that appear to match this Note directly. In the interest of submitting this information as soon as possible, I did not carry out any kind of exhaustive side-by-side check, nor have I employed any kind of automated plagiarism checker. I am, however, attaching an additional copy of Ms. Tshudy's paper where I have quickly just highlighted several examples that appear to be direct copies from Ms. Roger's Note. I assume the Law School has an automated plagiarism checker or other means to carry out a more thorough check. Incidentally, I did not see any citation or reference to Ms. Roger's Note in Ms. Tshudy's paper.

Please let me know if you need any further information.

Best regards,

James M. Gould
Adjunct Professor of Law
Penn State Dickinson Law
Jmg6487@psu.edu
Direct Dial: 610-993-4219

Table of Contents

Emerging Issues in Litigation and Protections Regarding the Progressive Switch from Patent to Trade Secret Protections in the Biotech and Pharmaceutical Industry

By Trisha Tshudy

I. Introduction

The United States has the largest and fastest growing drug market in the world, and the demand for generic drugs and biologics is steadily growing. Each year the pharmaceutical industry invests millions of dollars in promoting the research and development of new and generic drugs. With biotech discovery comes the need for businesses to retain their competitive advantage and for legislation and the judicial system to provide methods of doing so. While most pharmaceutical drug manufacturers still rely on patent protection in some capacity, companies are slowly including trade secrets in combination or as replacements to protect their intellectual property. This paper aims to explain the issues biotech and pharmaceutical companies are encountering in patent law that is leading to this change in intellectual property protection. The issues include It then tackles what issues are arising for those companies in attempting to litigate trade secret cases in a judicial system that requires some level of disclosure.

IMPORTANT NOTE For the following discussion, research and development which includes aspects of testing and are often susceptible to these infringements constitute the patent eligible category called "process." The following discussion is in reference to these "process" patents, also known as method patents and refer to the refinement of the manufacturing process.

II. Emerging Issues in Patent Protection

Patent protection was effective when the greatest value was in the product instead of the process. With the success of the industry and its exponential growth in competition, patents have now become less of a deterrent and more of an encouragement of competitors to capitalize off the work of their competitors. As the industry changes to more complicated products such as biologics, reverse engineering becomes less of a concern than patent scope. Additionally, the success of pharmaceuticals means a continuous goal of

refinement and improvement exists for patented products. But once the cookie cutter patent is made, the inability to modify patents to extend protections to improvements to these methods is a deterrent to relying on patents when developing the best product. Patents are becoming a cookie cutter of protection in a pastry industry; they are failing to adapt. Lastly, As the pharmaceutical industry builds, its exponential growth means that the ability of competitors to repeat the processes is greatly increased. So, lack of patent protection for processes greatly weakens the value that they have. Beyond that, even judicial rulings weaken patent protections themselves.

A. The patent system's failure to adjust to product and method refinement and recognize the value of process is a key force behind the movement of manufacturers to the use of trade secrets as a patent alternative.

The inability for patents to be adjusted to continued improvements and refinements of products prevents pharmaceutical companies from protecting their desire to create the best product available for their consumers and weakens them to be overcome by competitors. Additionally, as the industry advances creating more complicated products, the need for greater protection for processes and tests is sorely lacking. Also, more advanced products consequently create more uncertainty and difficulty in product standardization that lead to patent invalidity.

Patents lack the ability to alter patent protections until exclusivity period lapses. As the industry advances, manufacturing facilities and processes require frequent reassessment to ensure production of safer, more pure, more stable, and more potent products. Unfortunately, the patent and drug regulatory law traditionally utilized by manufacturers to protect their investments and simultaneously signal where innovation and investment are severely lacking. The manufacturer can either disclose critical aspects of the process in return for patent exclusivity periods or withhold information as trade secrets to prevent follow-on manufacturers from reverse-engineering their processes. A manufacturer should not feel restricted to wait until their exclusivity period lapses for them to obtain a higher degree of process control. The manufacturer

ideally wants the patent to be broad enough to protect subsequent innovation, while narrow enough to prevent subsequent biopharmaceutical manufacturers from reverse-engineering and pushing the biologic originator out of the market. [1] Yet competitors still capitalize on these abbreviated approval pathways.[2] As a result, significant opportunity exists in the regulatory framework to incentivize the research and development of manufacturing processes.

While some companies in the industry are advocating for data exclusivity extensions, the FDA's failure to regularly grant market exclusivity privileges for manufacturing process improvements alone has led companies to rely on trade secrets to fill the void. The issue of scope in the context of biopharmaceutical and biotech research arises in numerous and often conflicting situations. One such issue is whether these discoveries should be allowed the dual protection of both product and process patents,[3] which may overly broaden their scope.[4] Merges and Nelson submit that it is the process, rather than the product, which the inventor discovered. [4] The discovery of a new use for an existing product does not currently fit within patent protections, but some argue it should be awarded a process patent. [5] Other common discoveries such as those that improve the purity of a substance or to find a way to decrease the production costs by inventing synthetic versions of natural substances are considered by some to be double patenting and thus, should not be allowed.[5] In In re Wands, the Federal Circuit held that to claim a process, one must enable all the elements and components to perform such a process. This prevents inventors from patenting both the process and the product itself. [6] These data exclusivity grants are effectively like the very exclusionary right in patent law that Congress felt blocked competition and created artificial scarcity enough to create the Hatch Waxman safe harbor provision that is addressed in a more comprehensive assessment about alterations in patent scope leading to a rise in trade secret reliance. Beyond implementation issues, we will then take a look at how variations in scope a significant factor in the movement toward trade secret dependency are also.

B. Variations in patent scope are an additional cause for manufacturers to move to trade secret dependency.

As mentioned above, decrease in patent dependence represents a culmination of issues with patents such as increased complication of patent standards, lack of patent validity insurance, antitrust ruling eliminating financial alternatives to prevent validity litigation, dual patenting (product and process) discouragement, additional trade secret protections. Originally, federal legislation greatly favored and offered extended protection to patents over trade secrets. Patents were regulated directly through the Federal Food, Drug, and Cosmetics Act [7] and the Drug Price Competition and Patent Term Restoration Act of 1984 (the ***Hatch-Waxman*** Act), [8] and indirectly through regulations promulgated by the Food and Drug Administration (FDA). [9] Despite these protections, patent law is progressively weakening. The increasingly complicated nature of patent formation leads companies to be concerned about their standing and therefore, desire to protect it from litigation, but in a recent case, even that alternative was removed as an option.

Recent judicial decisions have weakened the protections garnered by patents. One such example is the expansion of the scope of the safe harbor provision of the Hatch-Waxman Act that allows competing drug manufacturers to "borrow" information within the patents of their competitors if it was specifically for the purpose of their own FDA submission. In the 2012 case *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* [10] the Federal Circuit held that via the safe harbor provision, competing generic pharmaceutical manufacturers could use each other's patented testing methods for pre-clinical research and manufacturing without incurring infringement liability. Although Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA) litigation not only gave its competitor use of Amphastar's testing method to develop its own generic, but the litigation delay also gave the competitions generic a year to monopolize the product resulting in profits over $260 million.[10] Thus, the Federal Circuit's holding in *Momenta* threatens manufacturers of generics with a devastating loss of previously available patent protection for testing methods. *Momenta* demonstrates that the scope of the safe

harbor provision has been expanded to such an extent that protection via method patents is no longer available.

Beyond rulings that weaken or eliminate the options of method or process protections through patents, rulings have also shown granted patents may be ultimately invalidated or temporarily invalidated leading to drastic consequences for the companies that worked so hard to obtain them. In *Pfizer v. Apotex*, the plaintiff patentee was granted a judgment of infringement and injunctive relief against the defendant which manufactured a generic version of the patentee's drug Norvasc before the expiration of the term of the patent. On appeal, the generic manufacturer challenged the ruling that the patent was not invalid for obviousness. The original drug was developed with a different salt of the key ingredient, amlodipine, but the patentee determined that use of a besylate salt was superior. The generic manufacturer certified that it believed the patent was invalid and unenforceable. If the patent was upheld as valid, the product would literally infringe the claims. The district court rejected the argument that the prior art rendered the invention of the claims of obviousness. On appeal, the court found the evidence of record easily shown by clear and convincing evidence that a skilled artisan would in fact have been motivated to combine the prior art to produce the specified compound. The court declared that it would have been obvious to one skilled in the art to make amlodipine besylate. That the patentee had to verify through testing the expected traits of each acid addition salt was of no consequence. The judgment of the district court was reversed because the subject matter of the patent claims in issue would have been obvious. Ultimately, the determination is one of weight and totality of the evidence. According to the Graham Test, the weight given to the patent examiner's determination should constitute only on factual consideration in a court's consideration of the totality of the circumstances. As wonderful as bright line rules are, the variability of individual cases often require this totality of the circumstance's tests. I believe in this case it was very important because it is dangerous to rely on one person's testimony no matter their authority or specialization, so it's a good pattern to develop.

Patent's strength depends on their approval ensuring coverage. Trade Secrets do not go through the same official approval process, so they do not have the extra level of verification that they meet

the definition and qualify for the requisite protection. Unfortunately, patents have been successively limited not only in scope, but even effectively after approval. This increased recognition that patents are no longer guaranteed after verification and can later be ruled invalid has weakened one of their strongest advantages over trade secrets. Patent invalidity now represents a comparable weakness to companies' own responsibility to make sure their trade secrets meet the definition required for protections to apply.

As improper patent writing has led companies' patents to fail. Some companies attempted to circumvent litigation and rulings on the validity of their patents through agreements with the competition to respect those patents. In FTC vs. Actavis, the Supreme Court considered whether a "reverse payment" settlement agreement can sometimes unreasonably diminish competition in violation of antitrust laws. [11] For my own notation, the reverse payment agreement entails that in a situation where Company A sues Company B for patent infringement, the two companies settle on terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B millions of dollars. Requiring the patentee to pay the alleged infringer is what constitutes the reverse as well as introduces the antitrust issue of discouraging competition. The 11th Circuit believed that the only pertinent question was whether the settlement agreement falls within the legitimate scope of the patent's exclusionary potential. The Supreme Court disagreed with measuring the length or amount of restriction based solely against the length of the patent's term and earning potential, and instead considered traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances (patent litigation). Whether a restraint lies beyond the limits of patent monopoly is the conclusion from this analysis and not the starting point. The Court further explains that the price of payout can be a direct indicator of the patentee's confidence in the validity of their patent and that reverse payments are a strong indicator of higher-than competitive profits which is a strong indicator of market power. The Court explained that litigation is more feasible than believed because these cases don't require an assessment of patent liability, they would only require an antitrust analysis. At the same time, the Court refused to follow the FTC's

request that the presumption should be that these agreements are unlawful and should only receive a "quick-look" approach before ruling so. The Court ruled that the complexities of these cases require the FTC to prove its case just as in other rule-of-reason cases. Aside from the antitrust implications, this ruling effectively eliminated a possible alternative of companies to mitigate the challenges to patent validity currently plaguing the system.

Until Congress decides to narrow the scope of the Hatch-Waxman provision, the patent system allows for dual or process patents, and the patent system allows for updates to patents within their period of coverage for companies who prioritize patient care to improve their methods and products, the industry will likely continue to progress towards using trade secrets for their intellectual property protection. As trade secret litigation grows, so do the emerging issues in litigation. Fortunately, a solution exists for generic drug manufacturers who wish to shield their tests and methods from the hungry eyes of their competitors. Despite the numerous regulations governing disclosure of information submitted to the FDA, including most notably the Freedom of Information Act (FOIA), generic drug manufacturers, using a heightened degree of care, can protect their testing methods and processes as trade secrets.

III. Trade Secret Law and the Potential Threats of Disclosure

While patent protection and the judicial system in general relies on disclosure, the trade secret protection depends on the lack of it. Therefore, proper treatment of trade secrets during litigation has led to the emergence of unique issues. Those issues include the threat of disclosure from mis definition, requests via the freedom information act, FDA use, discovery requests and the common law right of public access. including reconsideration of notification standards and the process of discovery.

A. Proper Compliance with the Definitions of Trade Secrets

Trade secrets do not require registration to qualify for trade secret protection, but their protection still depends on their ability to meet the definition and fall under its scope. Because of the nature of the product, the biotech and pharmaceutical industry still needs to pass FDA standards to be approved for medical use.

While trade secret law originally evolved under state common law, the Uniform Trade Secrets Act (UTSA), [12] extended trade secret recognition across states. [13] The USTA provides a broad definition, defining a trade secret as "information, held by one or more people, without regard to form, including a formula . . . method . . . technique … or process that: (1) derives independent economic value … from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." [14] It is important to note that while this is the general definition under the act, each manufacturer should be mindful of state specificities that could affect the application and the scope of the trade secret protection within their state. [15] The FDA provides their own definition for trade secrets which should also be considered particularly when submitting ANDAs. [16] Similarly the FDA, defines a trade secret as, "[A]ny commercial valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." [17] Because disclosure is essential to maintenance of trade secret protection the FDA offers that they "will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information. Except where specifically exempt pursuant to the provisions of this part, all FDA records shall be made available for public disclosure." [18, 19] Based upon the emphasis of protection's dependency on definition throughout all these regulations, the courts have used these as input to develop their own definition to standardize the scope for litigation measures. The courts currently specify that, "A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process." [20] Given the consideration of the trade secret definitions provided by the UTSA, state regulations, and the FDA in conjunction with the commitment to protections of trade secrets by

each, the responsibility is therefore placed in the business' hands to ensure their own compliance to definition.

B. Information Requests Via the Freedom of Information Act and the FDA's General Disclosure Policy

One example of the importance of proper compliance with these definitions is to empower these sources of protections to withstand the common law right of public access and even specific inquiries under the Freedom of Information Act (FOIA). The Freedom of Information Act controls the public disclosure of previously unreleased information from federal agencies and coincides with common law right of public access. [21] Specific requests can be made under the act for information that was required for FDA approval as well as information recognized within litigation. [22, 23, 24] Concerningly, section 3 of the FOIA that with few exceptions, "each agency, upon *any* request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, *shall* make the records promptly available to any person. [25] Additionally it requires the agency to perform reasonable searches for the information [26] and its findings in the format requested. [27]

While the FOIA aims to make as much agency information available to the public as possible, one of their few strict exemptions includes information that is "exempted from disclosure by statute." [28] if the statute is clear of its scope and cites to the FOIA. [29, 30] Additionally the FOIA does specify an exemption for "trade secrets and commercial or financial information obtained from a person and privileged or confidential," [31] without prior implementation in case law, manufacturers cannot be certain whether their information fits the scope of protection. This means that even a request submitted by competitors that reasonably details the information desired could lead the FDA to disclose valuable competitor information. [32] Fortunately, if the confidentiality of requested information is unknown or uncertain, the FDA will contact the entity who submitted the information and/or who will "be affected by its disclosure before determining" whether to disclose the information. [33] Any FDA rejection of a FOIA request "constitutes final agency

action that is subject to judicial review" [34] and the entity requesting the information has five days after notice to file suit. [35]. If a suit is filed, the person who declared confidentiality will be required to defend their claim in court. [36]. The ruling statute reads, "If the affected person fails to intervene to defend the exempt status of the records … the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public disclosure." [36] While the defense is not mandatory, it weighs heavily on the FDA's determination of disclosure. [36] If proper compliance with the definition causes an FOIA request to be limited or rejected, the competitor can also pursue disclosure through both the common law right of public access [37] and discovery request [38] pose additional threats for generic manufacturers who wish to protect their trade secrets.

C. Right of Public Access

The common law right of public access places trade secrets in direct contention with the court's desire to maintain open records of judicial proceedings. In *Nycomed US, Inc. v. Glenmark Generics, Inc.*, the Second Circuit emphasized the importance of public access to maintain an appearance of judicial legitimacy. [39] The Second Circuit declared in *Lugosh v. Pyramid Co. of Onondaga*, that judicial documents are presumed to be open to public access. [40] This presumption places the burden on trade secret confidentiality on the manufacturers. In *Stern v. Cosby*, the Second Circuit determined a three-part test to be applied to trade secret cases where a judicial document may fall under the common law right of public disclosure. [41] "First, the court must determine whether the documents are indeed judicial documents … Second, if the documents are judicial documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it." [42] The three-part test is an additional standard that, coupled with the general right to access, represents emerging issues in litigation that threatens the disclosure of trade secrets. Fortunately, the uniquely disclosure dependent nature of biotech trade secrecy means that the value of confidentiality tends to be weighed above the value of necessary public disclosure requirements. [43]

The first factor considers "whether the documents were judicial documents to which the public had a right of access." [44]Properly presented, the manufacturer could possibly end the inquiry here. The definition of "judicial documents," as discussed in Part II.C, [45] is "relevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings, [and] become documents to which the presumption of public access applies." [46] Therefore, the documents with the relevant trade secret information must be requested or submitted by the court in order for the definition to apply. The necessity of inclusion is unlikely unless the lawsuit concerns the method contained within the trade secret itself.

In addition, even if a court does request documents containing trade secrets, generic manufacturers could argue against disclosure based on the theory behind the common law right itself. For example, if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected, then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court's reputation. Inventors, manufacturers, and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks.

The second factor, "the weight of the presumption of disclosure," [47] would again, if properly presented, represent a strong argument against disclosure. As the court notes, "[T]he weight of the presumption depends on the 'role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal courts.' " [48] Therefore, the high value of a method being kept a secret from competitors would lessen the presumption of disclosure by the court and would weigh in favor the biotech manufacturers position. Additionally, the court finds that the inquiry is often based largely on whether the information sought to be disclosed essential to the litigation. The strongest evaluation of this is if the information can be used for a motion to dismiss. [48] Thus, for the purposes of a biotech manufacturer protecting a method, unless the test itself was of central importance to the litigation, the presumption would weigh in favor of nondisclosure.[48] Additionally, considering the

purpose of the doctrine, the presumption is logically stronger for information directly related to a motion to dismiss, because if the court dismisses a case based on a motion, it needs to show good cause for the dismissal.

Finally, the third factor, competing considerations against the presumption, [48] would again increase the likelihood that a biotech manufacturer would be able to win the battle over disclosure at this step, if they could not do so via steps one or two. As previously mentioned, courts' disclosure of lucrative, competition-driving methods and formulas to the public during litigation, will deter biotech manufacturers who desire protection from seeking it through judicial remedies. A manufacturer's active and vigorous defense of a trade secret is itself evidence of its value in the same way as its prerequisite investments to prevent disclosure are as well. The third factor directly corresponds to the same issue of litigation that deterred manufacturers from the use of patents for protection mentioned previously. Even if public disclosure occurs via the common law right of public access, it still causes the generic manufacturer to lose its competitive advantage, as well as the millions of dollars it invested in development of the secret. [49] Therefore, the presumption would favor disclosure. As demonstrated in *Momenta*, processes and methods offer a competitive advantage to generic companies who develop them, and their protection is essential to maintaining the value that incentivizes the industry overall. [49] Derogation of this incentive would cause adverse repercussions to the industry and society.

In *Nycomed*, we observe such an example. Here, the defendant sought to have the plaintiff's brief containing motions to amend the pleadings exempted from the common law right of public access, as the brief allegedly contained information that the defendant considered confidential. [50] The defendant argued that because two paragraphs of the plaintiff's motion contained confidential information related to the defendant's ANDA, this information was exempt from public disclosure. [50] The court, however, disagreed. This situation is distinguishable from one in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a method protected via trade secret law, because information protected as trade secret would not be found in an opposing party's brief to start with, if

it was actually a secret. It is the very element of unique and unknown qualities trade secrets necessitate. In *Nycomed*, the defendant sought to protect information contained in the plaintiff's brief. If the trade secret is correctly maintained, then it's only logical that an opposing party's motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place if the alleged trade secret were really a secret. The court reviewed the FDA's relevant provisions regarding the disclosure of pending ANDA's before noting that, "Certainly, any information that is already public, or is independently made public, cannot be deemed confidential." [50] Additionally the court mentioned that the FDA's regulations guarded only against disclosure by the FDA and not the common law right of public access. [50] Therefore, the presumption against disclosure during litigation should be cut in favor of the generic manufacturer if the generic manufacturer treats the method information allegedly within the scope of the common law right of public access as a legitimate secret.

D. Notice Requirements and Discovery Requests

In addition to the potential for disclosure due to a competitor's assertion of the common law doctrine of public access during litigation, the discovery rules could also pose a legitimate threat to biotech manufacturers who seek to protect their methods. As several cases have noted, there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil Procedure. [54] However, many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during discovery. [55] Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss 'trade secrets,' [56] and often work together to protect parties from disclosure. [57]

As mentioned, notice requirements and discovery requests also pose a threat to manufacturers who choose to protect their methods via trade secrets. The Federal Rules of Civil Procedure do not contain an absolute privilege for trade secrets that are requested during discovery or required during pleading to prevent summary judgment. [51] Despite this, Rules 26 and 45 are a potential avenue for biotech manufacturers to protect their method trade secrets from disclosure during these crucial steps in litigation. One such means is

through protective order. Rule 26 outlines a way in which a party may receive such a protective order from the court to guard against the disclosure of a trade secret [52]: "The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action." [52] Additionally, the rule states, "the court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" by several following methods. [52] One such method includes: "requiring that a trade secret or other confidential research development, or commercial information not be revealed or be revealed only in a specific way." [53] Although there is no *per se* protection of trade secrets in the Federal Rules of Civil Procedure, if the party seeking protection accepts the burden of proof and argues that the information should not be disclosed via Rule 26 and should be granted a protective order, the avenue of protection is maintained.

In *Massey Coal Services, Inc.*, the court elaborated on which circumstances would allow a court to issue a protective order pursuant to Rule 26(c)(1)(G) to prevent a party from having to disclose a trade secret during the discovery stage of litigation. [58] The plaintiff, Massey Coal, sued defendant, Victaulic, for various counts of breach of contract and misrepresentation. [58] According to the claim, the defendants manufactured and installed piping that the plaintiff used in its coal mines; when the pipes failed, the defendants admitted there was a problem but would not provide further information. [58] Before the hearing, the judge issued a protective order for "documents or other materials … subject to disclosure … [that are] confidential and should not be disclosed other than in connection with this action." [58] Pursuant to the protective order the defendant proceeded to disclose to the plaintiffs several documents marked 'CONFIDENTIAL', several of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail. Since the pipes were used to carry drinking water throughout the county, the plaintiffs made a motion to disclose the information to the Public Service Authority. [58] The defendant objected, invoking protection from Rule 26(c)(1)(G) [58] and arguing that the documents contained

commercially valuable information. [58] For the purposes of analysis, the court noted that Rule 26(c)(1) "treats equally a trade secret or other confidential commercial information."

Ultimately, the trial judge held that the documents were not protectable via Rule 26(c)(1), [58] but the reasoning of the court indicated crucial aspects of consideration for circumstances that would allow the opposite finding including instances that did not represent a public safety concern. Overall, the courts analysis is extremely valuable in understanding the scope of the protection offered under 26(c)(1). Accordingly, in order to get a protective order for discovered documents under 26(c)(1), the party possessing the documents must show "good cause" for protection, including, most relevantly, "undue burden or expense." [59] In other words, the defendants in this case argued that good cause was in the "severe economic damage" prevented by avoiding disclosure.[60] The court noted, "Broad allegations of harm, unsubstantiated by specific examples … do not satisfy the Rule 26(c) test. Moreover, the harm must be significant, not a mere trifle." [60] Additionally, the court recognized that defendants did not show full compliance with the trade secret standard because they failed to present any evidence that specific efforts were made to maintain the trade secrets, [60] object to disclosure of the documents to the plaintiffs, consider that the documents were contained in the court's public record, or failed to file a motion to seal the documents. [60] Therefore, the court reasoned that the documents were not compliant with trade secret standards and thus were not commercially valuable or protectable. [60] The trial judge specifically mentioned that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants, the embarrassment was not a concern of the court and would not protect the documents from disclosure. [60]

The *Massey* court's holding and reasoning showed that if a biotech manufacturer protecting a method via trade secret law wishes to prevent disclosure via Rule 26(c)(1), it must show "good cause" for a protective order by demonstrating "undue burden or expense." [61] Additionally, the biotech manufacturer must argue and present evidence that meets a certain level of specificity. In other words, they should provide the court with "specific examples or articulated reasoning" [62] to show that disclosure of the trade secret

would cause substantial economic harm to the manufacturer. Further, the manufacturer should show that this harm will be significant, and "not a mere trifle." [62] The Restatement of Torts provides some valuable factors commonly used to measure secrecy that would be a valuable resource towards meeting this standard. Such factors can include:

"[T]he extent to which the information is known by employees and others involved in the business … the extent of measures taken by the business to guard the secrecy of the information … the value of the information to the business and to its competitors … and the amount of effort or money expended in developing the information." [63]

Again, since methods take substantial time, effort, and funding to create, they are critical to any biotech manufacturer's market competitiveness and often represent greater value than the product itself because of their ability to apply to multiple products. [64] This increased value should heighten the importance of their protection. Biotech manufacturers should therefore heighten their consideration and implement higher measures and care to maintain their secrecy. Steps such as increase technological security, restriction of employee access, restriction of employees to specific subject matter, confidentiality agreements or noncompete agreements are just a few ways that can not only ensure greater protection of the trade secrets in general, but also incur a greater weight to the value of the trade secrets when it comes to the consideration by the courts. The more investments taken, the more value represented and the increased likelihood that privilege and confidentiality can be established allowing for greater protection throughout litigation.

E. Subpoenas

While Rule 26 combats general disclosure, Rule 45 is considered a way to prevent wrongful disclosure during discovery by protecting trade secrets from subpoenas. Rule 45 states, "To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information … " [65] In subsequent case law where a court is deciding whether to

quash a subpoena which seeks information marked as a trade secret, "a court must evaluate all the circumstances and balance, inter alia, the requesting party's need for the information and the potential prejudice imposed on the requested party." [66] The court also considers "the relevance of the discovery sought, the requesting party's need, and the potential hardship to the party subject to the subpoena." [67]

In addition, Rule 45 of the Federal Rules of Civil Procedure, [68] which governs subpoenas, could also benefit a biotech manufacturer seeking to protect a method through trade secret law during litigation. A manufacturer's trade secret will lose its value if disclosed; given the increased value of biotech methods currently observed in the industry, biotech manufacturers should understand the risks attributed to potential subpoenas so that they can preemptively prepare for the potential need to demonstrate, if necessary, why a method trade secret should not be disclosed. When determining whether to quash a subpoena that could potentially pose a threat of disclosure to a manufacturer's method trade secret, the court will balance the burden of disclosure with the potential need for the information argued in litigation. [69]

Although there is also no *per se* protection for trade secrets under Rule 45, it is likely that a manufacturer would be able to withstand disclosure of a method in the event of a subpoena. For example, *In re Fosamax* demonstrated that biotech manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure. A group of plaintiffs sued the defendant drug company, *Merck & Co.*, alleging that a drug they manufactured, Fosamax, caused adverse side effects.[70] The court issued a subpoena at the behest of the plaintiffs to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the guidance of the FDA.[70] Dr. Psaty stated that he never studied the drug in question and moved to quash the subpoena under Rule 45(d)(3)(B).[70] [71] Additionally, the defendant argued that allowing Dr. Psaty testimony was an uncertain and unnecessary risk to the potential disclosure of confidential information or trade secrets.[71] In response, the court balanced the burden between necessity of the testimony and the undue burden on the defendant to produce the information and ultimately quashed the subpoena. [71] The court further considered whether there is an undue burden on the defendant and assessed the personal hardship to the party protecting the information as well as

the wider social consequences of disclosing the information. [71] Here, the court noted that if Dr. Psaty were required to testify, "the resulting social impact would be far more serious. Compelling testimony from a third-party researcher risks chilling participation in beneficial public research." [71] Thus, the court recognized the value of trade secrets, suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them.

When comparing this case with the potential disclosure of a biotech manufacturer's method, manufacturers who receive subpoenas would rarely if ever be required to disclose trade secrets if called to testify. Even if the testimony sought had important implications to the case's subject matter or overall determination, the balancing of the burden between necessity of the testimony and the undue burden placed on the defendant would likely weigh in favor of quashing the subpoena. The personal hardship to the individual biotech manufacturer would be catastrophic, resulting in the loss of millions of dollars in profits or the loss of commercial market advantage and the industry would undergo similar repercussions to the rulings that led to the deterrence of trade secret use already discussed. [72] This time, possibly more severe without an alternative option currently in existence for biotech manufacturers to turn to. In addition, requiring biotech manufacturers to disclose trade secrets would not only have a chilling effect on beneficial scientific research and disincentivizing the investment, but could also have a much wider social impact that would weigh in favor of suppressing the subpoena for risk of unforeseen consequences.

Although trade secret law does not provide per se protection from disclosure, [73] biotech manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests, FDA use of the information, and the notice requirements, discovery, and public right to information emerging from litigation. Although FOIA encourages the broad disclosure of information obtained by a government agency or judicial body, a biotech manufacturer can demonstrate to the FDA's FOIA office that method trade secrets are immune from disclosure. The biotech manufacturer can point to the definition of trade secret adopted in Public Citizen Health to argue that the information qualifies as a trade secret, exempting it from disclosure. The FDA's

restriction to only disclosing protected information submitted to it by a third party under limited circumstances, provides biotech manufacturers with an avenue to combat the threat of disclosure from the FDA's one potential use. If the FDA recognizes that their power of disclosure is limited by and weighed against the property interest biotech manufacturers hold in their method trade secrets, and as long as biotech manufacturers properly comply with the FDA qualification standards for what constitutes a trade secret, the threat of disclosure by the FDA is manageable. Finally, threats of disclosure and emerging litigation issues, such as the common law right of public access, notice requirements, and discovery requests made by parties to a litigation, can also be overcome by biotech manufacturers in the ways outlined. The three-part test developed by the Second Circuit in *Stern v. Cosby* demonstrates that the judicial system's presumption favoring disclosure present in the common law right of public access can be avoided by biotech manufacturers protecting methods as trade secrets. Furthermore, biotech manufacturers could also protect their method trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45. Therefore, these avenues demonstrate that despite the emerging issues in the use of trade secrets over patent protection, biotech manufacturers could successfully rely on trade secrets to protect their research and development investments from competitors in ways patent law has not yet allowed.

IV. Conclusion

In summation, as argued by the dissent in Momenta that holdings and similar ones have used the safe harbor provision of the Hatch Waxman Act to render all patents on testing methods worthless, [74] an effect confirmed by later proceedings. [75] In light of the Momenta holding and other noted cases, opportunities for manufacturers to protect their intellectual property that constitutes methods or processes from use by their competitors has been removed from patent law. Fortunately, recently federalized protections for trade secrets are proving to be a viable alternative to patent protection for biotech and pharmaceutical manufacturers until Congress decides to act against these dangerous precedents. Therefore, biotech

manufacturers' increased dependence employs greater understanding and resolution of the issues that trade secret reliance has identified.

These emerging issues include the threat of disclosure from FOIA requests that can be prevented by proper compliance with the definitions set forth by statute and agencies, the threat of disclosure by the FDA's own use of information by limiting it through the second circuit's three-part test. Third, generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution, and that this purpose would be defeated if the court disclosed a manufacturer's extremely valuable information to competitors. Finally, biotech manufacturers can protect their trade secrets by invoking Federal Rules of Civil Procedure 26(c) against discovery requests for documents and Rule 45 against subpoenas. Therefore, trade secret law is a viable and stable alternative to patent protection for biotech and pharmaceutical manufacturers.

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EXHIBIT B

PENNSYLVANIA STATE UNIVERSITY
DICKINSON LAW

HONOR CODE

TABLE OF CONTENTS

CHAPTER ONE: ADMINISTRATIVE PROVISIONS

1.1 — Definitions:

1. Accused Student: A student suspected of an Honor Code Violation. The term includes a student who has made a Conscientious Admission but who has not reached agreement with the Honor Code Administrator.

2. Accuser: A member of the law school community who reports the alleged Honor Code Violation.

3. Community of Trust: Students of Dickinson Law expect that all members of the student body will conduct themselves in a manner consistent with the highest standard of honesty and integrity expected of those who enjoy the privilege of practicing law. This level of integrity accompanies the student in all dealings within the law school community.

4. Confidentiality: Information regarding an investigation of an alleged Honor Code Violation or Honor Proceeding shall not be made public, except as detailed in Chapter 8.

5. Conscientious Admission: A student's oral or written admission, presented to the Honor Code Administrator, of a possible Honor Code violation committed by that student.

6. Hearing Board: A panel, composed of three students and two faculty members drawn from the Honor Committee, convened to determine the validity of one or more alleged Honor Code Violations brought against an Accused Student and, when appropriate, to impose sanctions.

7. Honor Committee: The standing committee composed of six students and five faculty members, responsible for upholding and enforcing the Honor Code.

8. Honor Committee Chairperson: A student elected by a majority vote of the Student Bar Association to assist with the administration of the Honor Code.

9. Honor Proceeding: The formal adjudication of an alleged Honor Code Violation.

10. Law School Community: Includes all students, faculty, administrators and staff of Dickinson

Law.

11. Party: Either the Honor Code Administrator, the Presenter, or the Accused Student in an Honor Proceeding.

12. Plagiarism: Should be given its usual dictionary meanings: to steal and pass off (the ideas or words of another) as one's own; to use (a created production) without crediting the source or to commit literary theft, presenting as new and original an idea or product derived from an existing source. Plagiarism includes the copying or paraphrasing without acknowledgment of any material written or expressed by another person, and the submission of work written in whole or in substantial part by someone other than the student who submits the work as the student's own work. Plagiarism also includes the re-submission of work originally completed for another course and the giving or receiving of excessive assistance or making excessive use of the work of someone else in preparing an assignment, without faculty approval. What constitutes "excessive assistance" or "making excessive use of the work of someone else" is a matter for the course professor to decide and communicate in a timely manner to the students. Unless the course professor gives different instructions, "excessive assistance" should be construed with reference to the academic purpose of the assignment - to develop the student's research and writing skills and to evaluate his or her skills. A student may receive some counsel and suggestions from other people, e.g., another student, the course professor, so long as the paper is, in both pedagogical and literary senses, the work of the student.

13. President of the Hearing Board: A faculty member appointed by the Honor Code Administrator from among the two faculty members chosen to serve on the Hearing Board. The President presides over the hearing and prepares the Hearing Report.

1.2 — Purpose and Scope:

A. The goal of the Honor Code is to safeguard and promote the ideals of honor and integrity by prohibiting lying, cheating, stealing, and other dishonorable conduct of an academic nature.

B. The Honor Code does not relieve law students of the obligation to comply with other Penn State policies generally applicable to Dickinson Law student conduct, nor does it relieve law students of the obligation to comply with federal, state, and local regulations and with the jurisdiction of law enforcement authorities.*

C. Misconduct that may be subject to sanctions under the Honor Code, along with other misconduct, remains subject to the authority of the Dean and Faculty to maintain the educational process, the public reputation and institutional integrity of the law school, and the safety of the Law School Community. Such authority includes, without limitation, (1) the exclusion of a student from law school premises, (2) the imposition of grading sanctions, (3) the reporting of misconduct to law enforcement, bar admission authorities, and others, (4) the imposition of sanctions for misconduct in the law school admissions process, and (5) the imposition of sanctions upon former students who are no longer enrolled at the law school. In addition, the Honor Code does not preclude other remedies by authorities outside the law

* The Honor Code procedures described herein shall be used to adjudicate alleged substantive violations of generally applicable Penn State academic rules.

school, such as civil or criminal measures or bar-related sanctions, or by other units of The Pennsylvania State University or other educational institutions in which students subject to the Honor Code may be enrolled.

D. The procedures of this Code apply to all allegations of misconduct described herein.

E. An Honor Proceeding may be initiated until the law student's enrollment ends.

CHAPTER TWO: VIOLATIONS

2.1 — Violations:

A. Giving or securing any information about the content of an examination except as authorized by the examining professor.

B. Consulting or copying from any books, papers, notes, or other materials of any kind during an examination except as authorized by the examining professor.

C. Taking more time for completing an examination than is permitted except as authorized by the examining professor, Associate Dean for Academic Affairs (Associate Dean) or other designee of the Dean charged with exam administration.

D. Violating any other rules of Dickinson Law or a member of its faculty pertaining to the administration of examinations or the completion of course work.

E. Violating any rule set forth by Dickinson Law applicable to clinics, field placements, the moot court programs, law review and journals, or any legal writing or skills competitions recognized or supported by Dickinson Law, regardless of whether academic credit is given.

F. Violations of academic integrity. Violations of academic integrity include, but are not limited to, copying, Plagiarism, fabrication of information or citations, facilitation of acts of academic dishonesty by others, unauthorized possession of examinations, submitting work of another person or work previously used without informing the instructor, and tampering with the academic work of other students.

G. Authorizing the Plagiarism of one's work and its submission by another student in any academic pursuit that is recognized or supported by Dickinson Law, regardless of whether academic credit is given.

H. Removing, concealing, withholding, destroying, mutilating or otherwise abusing any library material without authorization.

I. Taking, using, concealing, withholding, destroying, mutilating, or otherwise abusing, without authorization, the academic property of another, including books, briefs, class notes, outlines, or any other items.

J. Consciously aiding or abetting any violation or attempted violation of this Honor Code.

K. Agreeing or conspiring to commit any violation of this Honor Code with another person irrespective of whether that person is subject to this Honor Code.

L. Misrepresenting any material fact in order to gain an unfair academic advantage or a benefit or service to which the student would otherwise not be entitled. This includes misrepresenting the student's academic achievement, record, or other activities in connection with seeking employment, financial aid, scholarships, scholarly awards, or admission into any program at an educational institution.

M. Using LEXIS, WESTLAW or other subscription services or technology furnished through Dickinson Law in an unauthorized manner.

N. Disruption or obstruction of teaching, research, administration or discipline regardless of location, including rules and procedures affecting health and safety.

O. Interfering with the investigation and disposition of any violation or alleged violation of the Honor Code, including but not limited to a knowingly false accusation, a misstatement to the investigating team, an unprivileged failure to testify, perjury, interference with witnesses, or intimidation of witnesses.

P. Failing to comply with a sanction imposed by the Honor Committee.

Q. Alteration, fabrication, or misuse of, or obtaining unauthorized access to Penn State or Dickinson Law documents, identification cards, or computer files or systems.

R. Falsely representing class attendance or participation in curricular and co-curricular activity.

CHAPTER THREE: RIGHTS OF THE ACCUSED STUDENT

The Accused Student has the right, at their own expense, to secure legal representation for any stage of the Honor Proceeding.

3.1 — Pre-Hearing Rights:

A. The Accused Student has the right to all evidence, including exculpatory evidence, at least one week prior to the Hearing. Evidence discovered during the week prior to the Hearing shall be immediately disclosed to the Accused Student.

B. The Accused Student has the right to request an open hearing, subject to the provisions of the Federal Education Right to Privacy Act (FERPA).

C. The Accused Student has the right to challenge potential Hearing Board members for cause.

3.2 — Hearing Rights:

A. The Accused Student has the right to offer any relevant evidence.

B. The Accused Student has the right to call witnesses.

C. The Accused Student has the right to examine the Accuser and other witnesses.

D. The Accused Student has the right to testify or to remain silent during any stage of the hearing.

E. The Accused Student has the right to make a closing argument.

3.3 — Appeal Rights:

A. The Accused Student has the right to a copy of the Hearing Report within 7 days after the Hearing.

B. The Accused Student has the right to appeal (see Chapter 7).

CHAPTER FOUR: HONOR COMMITTEE

4.1 — Members:

A. Six Dickinson Law students who shall be elected by the student body in a manner to be determined by the SBA to serve one-year terms as Honor Code Representatives. The SBA president shall select one Representative to serve as Honor Committee Chairperson (Chair).

B. Five faculty members who shall be appointed by the Dean. Faculty members shall serve one-year terms; however, such members shall be permitted to serve as many consecutive yearly terms as they, and the Dean, deem appropriate.

CHAPTER FIVE: PROCEDURE FOR HONOR PROCEEDINGS

5.1 — Reporting Procedure:

Any person affiliated with the law school may report a violation by submitting a memorandum to the Honor Code Administrator who shall be designated by the Dean. The written report shall include: (1) the name of the Accuser; (2) the name of the Accused Student; (3) the alleged violation; (4) the date of the alleged violation (if known); and (5) all facts relevant to the alleged violation, including the name of any person who may know of relevant facts.

5.2 — Preliminary Meeting:

A. The Honor Code Administrator shall meet with an Accused Student or a Student Making a Conscientious Admission as soon as practicable after receiving a report of an alleged violation.

B. The Accused Student or Student Making a Conscientious Admission and the Honor Code Administrator may resolve the matter by written agreement at any time. Any agreement resulting in the sanction of suspension or expulsion must be approved by the Dean.

C. If no agreement is reached, the Honor Code Administrator, in consultation with the Honor Committee Chair, shall determine whether probable cause exists to believe the Honor Code has been violated. If so, a Hearing shall be convened. If not, the case shall be dismissed.

D. Notwithstanding Section 5.2.C, a Student Making a Conscientious Admission who does not reach an agreement with the Honor Code Administrator may waive a finding of probable cause, admit to the violation(s), and proceed to Hearing on the issue of sanctions only.

5.3 — Hearing Board:

A. Upon a finding of probable cause, the Chair shall appoint members of the Hearing Board, schedule the time and place of a Hearing Board proceeding, and notify the Accuser, the Accused Student, and any witnesses to be called. The purpose of the proceeding shall be to determine whether the Accused Student has committed the charged violation of the Honor Code and, if so, to determine the appropriate sanction.

B. The Hearing Board shall consist of five Honor Committee members, three student members and two faculty members, appointed by the Chair. The Honor Code Administrator and Chair shall not serve on a Hearing Board.

C. The Chair shall select one of the faculty members to be President of the Hearing Board.

D. The Honor Code Administrator, or the Dean's designee, shall serve as the Presenter and present the case against the Accused Student.

5.4 — Pre-Hearing Procedure:

A. Prior to the hearing, the Presenter shall distribute the complaint and any other relevant information to the members of the Hearing Board.

B. The Presenter and the Accused Student must provide the President of the Hearing Board with a list of all witnesses that they intend to question at the Hearing.

C. The Presenter and the Accused Student must arrange for their witnesses to testify at the Hearing; the Honor Committee shall provide reasonable assistance.

5.5 — Conduct of the Hearing:

A. Unless the Hearing is open, only persons involved in the Honor Proceeding may attend.

B. The Honor Code Administrator or the Dean's designee shall present the case against the Accused Student, including an opportunity for rebuttal.

C. The Accused Student may present his/her case.

D. Witnesses shall be called individually and subject to examination, cross examination and redirect examination by the parties. Hearing Board members may question witnesses.

E. The President of the Hearing Board shall arrange for testimony to be electronically preserved.

F. The President of the Hearing Board shall have the power to rule on procedural matters.

G. At the conclusion of testimony, the Hearing Board shall deliberate privately. The Hearing Board may reconvene, together with the parties, to ask additional questions or reexamine witnesses. Only the Hearing Board may recall witnesses. The Hearing Board shall vote upon the factual elements that are essential to a finding of whether the Accused Student violated the Honor Code. A violation is established only if at least four of the five members of the Hearing Board so find.

H. If the Hearing Board does not find that a violation of the Honor Code has occurred, it shall dismiss the charges and immediately notify the Accused Student.

I. If the Hearing Board finds that a violation of the Honor Code has occurred, it shall immediately notify the parties, who shall then be afforded the opportunity to address the issue of the appropriate sanction(s). At the conclusion of this presentation, the Hearing Board shall determine what sanction(s) to impose in accordance with Chapter 6.

J. The Hearing Board shall reconvene for the imposition of the sanction(s).

K. An Honor Case shall be closed when no violation of the Honor Code was found to have occurred; a violation was found to have occurred, and no appeal is requested; the appeal is terminated.

Imposition of any sanction(s) shall commence once the case is closed.

5.6 — Rules of Evidence:

A. The President of the Hearing Board shall rule on the admissibility of evidence based on relevance and fairness; the Hearing Board shall not be bound by formal rules of evidence.

B. The Hearing Board may draw an adverse inference against an Accused Student who, upon request, fails or refuses to produce relevant real evidence in his/her possession or control.

C. The Hearing Board may draw an adverse inference against the Accused Student for remaining silent during any stage only in determining the appropriate sanction(s) after finding a violation.

5.7 — Burden of Persuasion:

The Presenter must prove the facts of the case by clear and convincing evidence. In order to find the Accused Student guilty of an Honor Code Violation, four of the five members of the Hearing Board must be persuaded that (1) the Presenter proved the alleged facts and (2) the conduct proved by the Presenter violates the Honor Code. Following a determination of guilt, the Hearing Board may impose sanctions. Four of the five members of the Hearing Board must approve sanctions that are imposed. When the Hearing Board imposes a sanction of suspension or expulsion, however, all members of the Hearing Board must agree.

CHAPTER SIX: SANCTIONS FOR VIOLATIONS

In choosing a sanction, the Hearing Board must consider the items in Section 6.1 but may also consider any other relevant information. Additionally, the sanctions that may be imposed by the Hearing Board upon finding of a violation of the Honor Code are not limited to those in Section 6.2.

6.1 — Criteria:

A. The nature and seriousness of the violation, including the potential harm to the academic integrity of the law school community.

B. The circumstances of the violation, including any aggravating or mitigating factors.

C. The need to uphold and promote respect for the Honor Code and to deter future violations by the Accused Student and others.

D. The opportunity afforded in fashioning a sanction to make amends for the Accused Student's transgression(s) against the law school community.

E. Whether the student made a Conscientious Admission.

F. The extent to which the Accused Student cooperated or was forthright during the investigation and/or Honor Proceeding.

G. Any comments relevant to sanctions that the Accused Student and his/ her representative make.

H. Whether the Accused Student gained, or acted with the intent to gain, academic benefit.

6.2 — Possible Sanctions:

A. An order to return, replace or pay for the property of the victim.

B. An oral or written reprimand not to be included in the student's record.

C. A written reprimand to be included in the student's record.

D. Denial of credit for a course, with an appropriate transcript entry.

E. Suspension or denial of library or other privileges or offices.

F. Dismissal from the Honor Committee.

G. An order requiring appropriate compulsory service to the law school community.

H. Suspension from academic and/or non-academic law school activities for a stated period.

I. Expulsion from Dickinson Law.

CHAPTER SEVEN: PROCEDURE FOR APPEALS

7.1 — Appeals:

A. A written Appeal must be submitted to the Dean within 7 days of the Accused Student's receipt of the Hearing Report. The Appeal must include the reason for review and the remedy sought.

B. The Dean has full discretion to consider any materials relevant to the case. The Dean has the power either to remand the case to the Hearing Board for further consideration, or to impose lesser sanctions than those imposed by the Hearing Board, or to affirm the sanction(s) imposed by the Hearing Board. The Dean shall provide a written rationale when remanding a case or imposing a lesser sanction. *The Dean shall not have the authority to impose sanctions that are more severe than those imposed by the Hearing Board.*

CHAPTER EIGHT: DISCLOSURE OF DISPOSITIONS

The Honor Code Administrator shall periodically publish reports on the matters disposed consistent with FERPA.

CHAPTER NINE: AMENDMENT PROCESS

1. Any person affiliated with the law school may submit an amendment proposal to the SBA.
2. The SBA shall determine which amendments will be placed on the ballot for student vote.
3. Amendments approved by a majority of students voting shall go to the faculty for final approval.

STATEMENT OF ETHICS AND INTEGRITY

I swear or affirm to uphold the principles and goals of the Honor Code as espoused herein.

The central purpose of this Honor Code is to sustain and protect the Community of Trust in which all members of Dickinson Law community can enjoy the freedom to develop their intellectual and personal potential.

The duty of every member of this community shall be to safeguard and promote the ideals of honor and integrity within Dickinson Law. The Honor Code therefore proscribes dishonorable conduct, including lying, cheating, and stealing. It further prescribes honesty and presumes as much of its members.

It is the duty of all members of Dickinson Law community to act in accordance with this Honor Code, and to be responsible to one another for violating and enforcing this Code.

EXHIBIT C

BIOTECH, PHARMACEUTICALS AND THE LAW

Professor Gould

Mondays 4:00pm-5:50pm KH 013

COURSE POLICIES

Fall 2021

BIOTECH, PHARMACEUTICALS & THE LAW ("BPL") COURSE POLICIES [1]

Course Description — This course examines legal aspects of the pharmaceutical and biotech sectors, including selected FDA and NIH-related laws and regulations; issues related to COVID-19; IP issues affecting the pharmaceutical and biotech sectors (including patent strategy and litigation); genetic testing; medical and data privacy; direct-to-consumer marketing of genetic tests; telemedicine; commercialization of pharmaceutical and biotech products; genetic property; and ownership of human tissues and cell lines. This course will also cover ethical considerations related to several of the highlighted topics.

Course Objectives — By the end of the course, students should have a basic appreciation of legal and regulatory issues relevant to the biotech and pharmaceutical fields and experience researching those issues. In addition, students should have a better understanding of various roles lawyers have in the biotech and pharmaceutical fields.

Assignments & Required Texts — Each week, usually by the end of the day on Wednesday at the latest, a Weekly Assignment Memo will be posted on Canvas, which will include details on the reading assignments for the week ahead. Reading assignments for this course will be drawn from our course's basic text (Goodwin *et al.*, listed below) as well as additional sources, including e-reserves (available in the "Library Reserves" link on Canvas), Lexis and Westlaw, and the internet. You will also be reading research materials for your written and oral assignments throughout the term.

- Goodwin, Tu & Paris, BIOTECHNOLOGY, BIOETHICS, AND THE LAW, Carolina Academic Press 2015 (ISBN 978-0-82055-985-8).

My Contact Information:

- Email: jmg6487@psu.edu;
- Office phone: (610) 993-4219 (usually set up to ring through to my cell).
- Office hours: by appointment (typically Monday afternoons before or after class).

ASSIGNMENTS AND GRADING

A student's grade in BPL will be based on the following:

A. BPL slide presentation covering a current or emerging legal topic/issue relating to the biotech and/or pharmaceutical fields (20% of final grade). Topic of student's slide presentation must be different from the topic student selects for the BPL final paper. Details are set forth below.

B. BPL final paper examining in detail a current or emerging legal topic/issue relating to the biotech and/or pharmaceutical fields (58% of final grade). Details are set forth below.

C. Oral presentation of your final paper (4% of final grade)

D. Class participation (18% of final grade)

[1] BPL Course Policies and Syllabus are subject to change in accordance with course needs. Both are adapted from corresponding documents previously prepared by Professor Gaudion for one of her courses.

A. SLIDE PRESENTATION COVERING A CURRENT OR EMERGING LEGAL TOPIC/ISSUE RELATING TO THE BIOTECH AND/OR PHARMACEUTICAL FIELDS (Weeks 6-10, one or two students each week)

During the middle phase of our course (expected weeks 6-10), each student will present a slide presentation covering a current or emerging legal topic/issue relating to the biotech and/or pharmaceutical fields. Your slide presentation will represent **20%** of your final grade. The topic selection process will be similar to the topic selection process for your final paper project (explained in detail below). However, the topic you select for your slide presentation must be ***different*** from the topic you select for your final paper. During our first two or three classes, we will discuss proposed topics as you will need to select your slide presentation topic relatively early in the semester. I will be glad to provide guidance through topic selection and preparation of your presentation. With regard to duration, your slide presentation should not exceed 20 minutes as I will only be allotting 30 minutes for each student's live presentation and want to reserve about 10 additional minutes to account for questions and class discussion.

B. FINAL PAPER EXAMINING A CURRENT OR EMERGING LEGAL TOPIC/ISSUE RELATING TO THE BIOTECH AND/OR PHARMACEUTICAL FIELDS

Your final paper for this course will be due on **December 15, 2021**, and will represent **58%** of your final grade. As indicated above, your paper must engage subject matter of this course while examining a current or emerging legal topic/issue relating to the biotech and/or pharmaceutical fields. I will work with you early on to guide you in this project, and I recommend conferring with me more than once or twice over the course of the term to discuss your paper. (My office hours are by appointment — typically Monday afternoons before or after class, and you can also schedule a call with me since I'm not usually in Carlisle beyond Mondays). As also indicated above, we will discuss proposed topics during our first two or three classes, and the topic you select for your slide presentation must be different from the topic you select for your final paper. Since the dates for student slide presentations will be staggered, I will refrain from designating a specific class-wide deadline for the designation of slide presentation topics, but I will, however, require all students to email me their proposed topic selections for their final papers by **Wednesday, October 6th** at the latest. That said, proposed topics can subsequently be modified with my approval if needed.

Details regarding instructions for BPL Final Papers include the following:[2]

1. BPL Final Papers must comply with the following submission and formatting requirements unless permission to deviate is obtained well ahead of time: a minimum of 20 double-spaced, typed pages, excluding footnotes/endnotes/references, using one-inch margins and twelve-point font (approx. 5000 words minimum, excluding footnotes/endnotes/references).
2. Citations shall conform to "The Bluebook".
3. Students must submit an original manuscript.
4. Students shall not engage in plagiarism or other dishonesty or deception. Students guilty of such conduct will receive a failing grade, will be denied credit for the course, and will be subject to other sanctions pursuant to Dickinson Law's Honor Code.

[2] Instructions 1-5 for the BPL Final Paper conform to rules which apply to seminar papers at Dickinson Law.

5. Students shall not receive excessive assistance or make excessive use of the work of someone else in preparing a BPL Final Paper, regardless of whether they give credit to that person.
6. The absolute deadline for submission of BPL Final Papers is **December 15, 2021**. The due date for submission of proposed topics for the final paper is **October 6th**, and the due date for submission of students' research plan for the final paper is **October 18th**.

A sample student paper, which was provided by another Dickinson Law professor and conforms to the rules above, has been posted in Canvas.

A research plan for your paper (around 400-500 words or so) is due by **Monday, October 18th**. Your plan should include a clear statement of the issues that you will be handling, as well as your general research plan, your proposal for analyzing the issues, and your thesis.

You will present your paper at one of the last two class sessions (see Section C below). The absolute deadline for your final paper will be **December 15, 2021**, and your final paper must be sent directly to me by email (jmg6487@psu.edu) by 11:59pm on that date.

C. ORAL PRESENTATION OF YOUR FINAL PAPER

As indicated above, you will present your final paper at one of the last two class sessions (approximately 10 minutes per student). Your presentation of your paper will represent **4%** of your final grade.

D. CLASS PARTICIPATION REQUIREMENT, INCLUDING PRESENTATION OF SELECTED COURT CASES

In this course, most class sessions will include a mix of lecture and dialogue. I expect you to attend every session, to have read and thought about the materials, and to be prepared to discuss them. I generally rely on volunteers to answer questions, but I will occasionally call on students at random. I do this for two reasons. First, active discussion is an essential part of learning the material in this course. Second, good lawyers must be able to effectively apply existing legal rules to current problems and to communicate their analyses to their clients and others. Participation will represent **18%** of your final grade.

GENERAL COURSE POLICIES

Students must complete each assignment in good faith and in a timely fashion. Written assignments will be evaluated based upon the quality of legal analysis, research, and writing skills and style. In addition, the assignments will be evaluated on compliance with the instructions for the assignment, including due dates, preparation for conferences, and formatting requirements.

Additional information on the law school's grading and evaluation policies is available in the Dickinson Law Student Academic Handbook.

Timeliness and Penalties for Late or Incomplete Assignments — In their professional roles, lawyers face deadlines with significant (and sometimes severe) consequences. Thus, lawyers are

expected to submit work in a timely fashion. The expectations are the same for this class. Penalties for late submissions, absent compelling and unusual circumstances, likewise will be significant.

For unexcused delays in submitting a graded assignment, late penalties will be imposed cumulatively as follows:

- If a student submits a graded assignment after the deadline, a minimum 20% grade reduction will be imposed automatically.
- If a student submits a graded assignment *more than 24 hours* after the deadline, an additional 20% grade reduction will be imposed automatically for each 24-hour period.

A pattern of late submissions and/or incomplete preparation for any assignments (graded or ungraded) may also result in a deduction of the student's final grade in the course.

Penalty for Unprofessional Submissions — Legal writing is professional writing. Judges and supervising attorneys expect a professional level of writing. Indeed, a court may refuse to accept a submission that is replete with errors. Failure to proofread negatively affects an attorney's credibility. Therefore, all written submissions must be proofread and polished to remove typographical, spelling, formatting, citation, and other errors.

Extensions — Extensions will be granted only for serious matters beyond the student's control. If you find yourself in an emergency situation, contact me. Exceptions may be made for legitimate emergencies. If possible, request an extension before the assignment's due date.

Computer and Technology-Related Problems — Sometimes because of software incompatibility with Canvas, students will find that the format from their software is not compatible with the Canvas software, and students will lose the formatting in the paper, the spacing or font size will be different, or other problems will arise. Please work out format incompatibilities before an assignment is due. Also, please be aware that uploading assignments to Canvas can take several minutes, and it is the time stamp once the file is uploaded to Canvas that is used to determine the timeliness of submissions. Computer problems, including e-mail or Canvas problems, should be foreseen and are not grounds for an extension.

Communications

Changes in class meeting times or assignments may be necessary during the semester, and you will be notified of the changes as early as possible. ***You are responsible for checking your e-mail daily for changes in meeting times or assignments.*** Further, you are responsible for complying with announcements regarding revisions to course readings and assignments.

Workload Expectations

The American Bar Association standards for accrediting law schools contain a formula for calculating the amount of work that constitutes one credit hour. According to ABA Standard 310(b)(1),

> a "credit hour" is an amount of work that reasonably approximates: (1) not less than one hour of classroom or direct faculty instruction and two hours of out-of-class student work per week for fifteen weeks, or the equivalent amount of work over a different amount of time."

This is a 2-credit hour class, meaning that we will spend two 50-minute blocks of time together each week (back-to-back blocks with a 10-minute intermission in this case). Applying the ABA standard to the number of credits offered for this course, you should plan to spend *a minimum* of 6 total hours per week (2 hours in class and 4 hours preparing for class) on course-related work.

Attendance Policy

In the professional workplace, regular attendance is expected and unexcused absences and/or tardiness are not permitted. The expectations are the same for this class. ***Failure to attend class will result in a one-point deduction from your final grade for each absence in excess of four (4) absences***. For the purposes of determining absences, please note that ***one absence is defined as missing one 50-minute portion of a given 100-minute class block. Thus, if you were to miss 2 BPL 100-minute classes, this would count as 4 absences*** and you would be penalized one-point; and if, for example, you were set to receive an A- in the class, a one-point deduction would drop your grade to a B+. There will be no distinction made between excused and unexcused absences. If extreme circumstances arise, however, please notify your professor to discuss whether an adjustment to the class attendance policy is appropriate. Further, at the professor's discretion, students who have more than four (4) unexcused class absences may fail the course. Even excused absence and lateness may result in grade reduction or failure if they have impaired your class performance or your acquisition of course material.

For an absence or lateness to be excused: (a) it must be due to an illness, family or other emergency, or job interview; and (b) you must give reasonable advance notice (by e-mail) of the absence or lateness. For emergencies where prior notice is not possible, prompt after-the-fact notice is appropriate. Also, for any absence or lateness, you are responsible for the material that is covered on the day that you missed.

Class Recording Policy & Consent

This course is in a classroom equipped with audiovisual telecommunications equipment that will record each class meeting automatically as it occurs. These recordings will include images and voices of the professor and some or all of students enrolled in the course. The purpose of the recordings is to permit the professor and students enrolled in the course to access the recordings, according to rules established by the professor, outside of the regularly scheduled class period. Access will be controlled via a secure course management platform, such as Canvas. Access to the recordings will be restricted to students enrolled in the course, the professor, and those University IT personnel necessary to maintain the system. Access will end on the last day of the final exam period.

By registering for this course, you consent to the law school's making and displaying class recordings within the scope of the rules described above.

A student enrolled in this course may request permission to view a recording for one or more classes missed as the result of an excused absence. The professor may permit the class recording to be made available. To request permission, submit the request through the online access request system available on Canvas, including your reason for requesting permission. Access will end on the last day of the final exam period.

Inappropriate Use of Class Recordings or Course Materials

A student may not record any part of a class by any means without prior express authorization of the faculty member. If a student receives faculty authorization to make an audio recording of a class or to access a class recording, the student may not copy or download such recording to a computer or other device, distribute it to any other person, or use the recording for any purpose other than personal education and study. Unauthorized recording, distribution, or use of a class recording is a violation of the Dickinson Law Honor Code.

A student may not use course materials such as slides or other documents posted on Canvas for any purpose other than personal education and study and may not disseminate, publish, or alter course materials without prior express authorization of the faculty member. Unauthorized use of course materials is a violation of the Dickinson Law Honor Code.

The Dickinson Law Honor Code covers unauthorized recording and unauthorized use of class recordings and course materials. It prohibits "Taking, using . . . or otherwise abusing the property of another, including, without limitation, books, briefs, class notes, outlines, or any other academic items, without authorization."

Inclusive Learning Environments, Names/Pronouns and Self-Identification

In any environment in which people gather to learn, it is essential that all members feel as free and safe as possible in their participation. To this end, it is expected that everyone in this course will be treated with mutual respect and civility, with an understanding that all of us (students, faculty, guests, and teaching assistants) will be respectful and civil to one another in discussion, in action, in teaching, and in learning. There is an important line between challenging an idea and challenging the person who expresses that idea. Conflicting views will create dynamic discussions and help each of us refine our thinking. However, personal attacks whether express or subtle will stifle communication. Let us work together to think and speak critically of ideas and not of each other.

The Pennsylvania State University recognizes the importance of a diverse student body, and we are committed to fostering equitable classroom environments. I invite you, if you wish, to tell me how you want to be referred to both in terms of your name and your pronouns (he/him, she/her, they/them, etc.). The pronouns someone indicates are not necessarily indicative of their gender identity. Visit **Transgender and Non-Binary at Penn State** to learn more. Additionally, how you identify in terms of your gender, race, class, sexuality, religion, and dis/ability, among all aspects of your identity, is your choice whether to disclose (e.g. should it come up in classroom conversation about our experiences and perspectives) and should be self-identified, not presumed or imposed.

IMPORTANT PENN STATE UNIVERSITY POLICY STATEMENTS + COVID-19 RELATED POLICIES

Academic Integrity Statement

Academic integrity is the pursuit of scholarly activity in an open, honest and responsible manner. Academic integrity is a basic guiding principle for all academic activity at The Pennsylvania State University, and all members of the University community are expected to act in accordance with this principle. Consistent with this expectation, the University's Code of Conduct states that all students

should act with personal integrity, respect other students' dignity, rights and property, and help create and maintain an environment in which all can succeed through the fruits of their efforts. Academic integrity includes a commitment by all members of the University community not to engage in or tolerate acts of falsification, misrepresentation or deception. Such acts of dishonesty violate the fundamental ethical principles of the University community and compromise the worth of work completed by others.

The Dickinson Law Honor Code provides that: "Students of Dickinson Law expect that all members of the student body will conduct themselves in a manner consistent with the highest standard of honesty and integrity expected of those who enjoy the privilege of practicing law. This level of integrity accompanies the student in all dealings within the law school community."

Disability Accommodation Statement

Penn State and Dickinson Law welcome students with disabilities into the University's educational programs. Students with temporary or permanent medical conditions or physical, cognitive, or psychological disabilities may be able to receive accommodations to eliminate barriers to their success. Accommodated students do not receive an advantage over others; rather, accommodations allow such students to not be at a disadvantage relative to other students as a result of conditions beyond their control. The Office of Student Services handles student disability accommodations at Dickinson Law.

In order to receive consideration for reasonable accommodations, you must complete the disability accommodation intake form, collect the required documentation, and schedule and participate in an intake interview. If the documentation supports your request for reasonable accommodations, the Office of Student Services will provide you with an accommodation letter listing both classroom and testing related accommodations. Classroom accommodations will be shared by Dean Dodge directly with faculty members. Testing accommodations are never to be shared with faculty members in order to maintain the anonymous grading process. A Testing Accommodation Access Request must be submitted for each quiz, midterm, final exam or other assessment for which a student seeks access their testing accommodations.

Students are strongly encouraged to address their accommodation needs as early in the semester as possible. An accommodation letter must be approved every semester before accessing accommodations.

Counseling and Psychological Services Statement

Many students at Penn State and Dickinson Law face personal challenges or have psychological needs that may interfere with their academic progress, social development, or emotional wellbeing. The law school and Carlisle community offer a variety of confidential services to help you through difficult times, including individual and group counseling, crisis intervention, consultations, online chats, and mental health screenings. These services are provided by staff who welcome all students and embrace a philosophy respectful of clients' cultural and religious backgrounds, and sensitive to differences in race, ability, gender identity and sexual orientation.

Franco Psychological Associates, PC
26 State Avenue, Suite 101

Carlisle, PA 17015
Phone: 717-243-1896
Website: https://www.francopsychological.com/ (Links to an external site.)

Contact Helpline (24 hours/7 days/week)
Phone: 717-249-6226
Website: http://www.contacthelpline.org/ (Links to an external site.)

Penn State Crisis Line (24 hours/7 days/week): 877-229-6400
Crisis Text Line (24 hours/7 days/week): Text LIONS to 741741

The Office of Student Services
Lewis Katz Hall, Suite 022
Phone: 717-240-5209
Schedule a Meeting: https://calendly.com/deandodge

Education Equity/Report Bias Statement

Penn State and Dickinson Law take great pride in fostering a diverse and inclusive environment for students, faculty, and staff. Acts of intolerance, discrimination, or harassment due to age, ancestry, color, disability, gender, gender identity, national origin, race, religious belief, sexual orientation, or veteran status are not tolerated and can be reported through the Office of Student Services or via the Educational Equity Report Bias webpage: http://equity.psu.edu/reportbias/ (Links to an external site.). Sexual or gender-based discrimination, harassment or misconduct may also be reported via the Title IX Response Incident Report Form: https://titleix.psu.edu/filing-a-report/ (Links to an external site.).

EXHIBIT D

9864 words 29% matched		13089 words 21% matched
The United States has the largest and fastest growing drug market in the world , and the demand for generic drugs	<< 21 words >>	The United States has the largest and fastest growing drug market in the world , and the demand for generic drugs
millions of dollars in promoting the research and development of new and generic	<< 13 words >>	millions of dollars in promoting the research and development of new and generic
to retain their competitive advantage	<< 5 words >>	to retain their competitive advantage
most pharmaceutical drug manufacturers	<< 4 words >>	most pharmaceutical drug manufacturers
the Federal Food , Drug , and Cosmetics	<< 8 words >>	the Federal Food , Drug , and Cosmetics
and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act)	<< 17 words >>	and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act)
and indirectly through regulations promulgated by the Food and Drug Administration (FDA)	<< 14 words >>	and indirectly through regulations promulgated by the Food and Drug Administration (FDA)
the safe harbor provision of the Hatch-Waxman Act	<< 8 words >>	the safe harbor provision of the Hatch-Waxman Act
allows competing drug manufacturers to " borrow " information within the patents of their competitors	<< 15 words >>	allows competing drug manufacturers to " borrow " information within the patents of their competitors

9864 words 29% matched		13089 words 21% matched
Momenta Pharmaceuticals , Inc. v. Amphastar Pharmaceuticals ,	<< 8 words >>	Momenta Pharmaceuticals , Inc. v. Amphastar Pharmaceuticals ,
held that via the safe harbor provision , competing generic pharmaceutical manufacturers could use each other	<< 16 words >>	held that via the safe harbor provision , competing generic pharmaceutical manufacturers could use each other
testing methods for pre-clinical research and manufacturing without incurring infringement	<< 10 words >>	testing methods for pre-clinical research and manufacturing without incurring infringement
Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA)	<< 16 words >>	Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA)
holding in Momenta threatens manufacturers	<< 5 words >>	holding in Momenta threatens manufacturers
with a devastating loss of previously available patent protection for	<< 10 words >>	with a devastating loss of previously available patent protection for
safe harbor provision has	<< 4 words >>	safe harbor provision has
. Fortunately , a solution exists for generic drug manufacturers who wish to shield their tests and methods	<< 18 words >>	. Fortunately , a solution exists for generic drug manufacturers who wish to shield their tests and methods
from the hungry eyes of their competitors . Despite the numerous regulations governing disclosure of information submitted to the FDA ,	<< 46 words >>	from the hungry eyes of their competitors . Despite the numerous regulations governing disclosure of information submitted to the FDA ,

9864 words 29% matched		13089 words 21% matched
including most notably the Freedom of Information Act (FOIA) , generic drug manufacturers , using a heightened degree of care , can protect		including most notably the Freedom of Information Act (FOIA) , generic drug manufacturers , using a heightened degree of care , can protect
as trade secrets .	<< 4 words >>	as trade secrets .
, FDA use ,	<< 4 words >>	, FDA use ,
the common law right of public access	<< 7 words >>	the common law right of public access
to qualify for trade secret protection ,	<< 7 words >>	to qualify for trade secret protection ,
trade secret law originally evolved under state common law , the Uniform Trade Secrets Act (UTSA)	<< 18 words >>	trade secret law originally evolved under state common law , the Uniform Trade Secrets Act (UTSA)
information , held by one or more people , without regard to form , including a formula . . . method . . . technique	<< 25 words >>	information , held by one or more people , without regard to form , including a formula . . . method . . . technique
or process that : (1) derives independent economic value	<< 11 words >>	or process that : (1) derives independent economic value
from not being generally known to , and not being readily ascertainable by proper means by , other persons who can obtain economic value from its disclosure or use ; and is the subject of efforts that are reasonable under the circumstances to maintain its	<< 45 words >>	from not being generally known to , and not being readily ascertainable by proper means by , other persons who can obtain economic value from its disclosure or use ; and is the subject of efforts that are reasonable under the circumstances to maintain its

9864 words 29% matched		13089 words 21% matched
, each manufacturer should	<< 4 words >>	, each manufacturer should
the scope of the trade secret protection	<< 7 words >>	the scope of the trade secret protection
will make the fullest possible disclosure of records to the public , consistent with the rights of individuals to privacy , the property rights of persons in trade secrets and confidential commercial or financial	<< 34 words >>	will make the fullest possible disclosure of records to the public , consistent with the rights of individuals to privacy , the property rights of persons in trade secrets and confidential commercial or financial
Except where specifically exempt pursuant to the provisions of this part , all FDA records shall be made available for public	<< 21 words >>	Except where specifically exempt pursuant to the provisions of this part , all FDA records shall be made available for public
A trade secret may consist of any commercially valuable plan , formula , process , or device that is used for the making , preparing , compounding , or processing of trade commodities and that can be said to be the	<< 41 words >>	A trade secret may consist of any commercially valuable plan , formula , process , or device that is used for the making , preparing , compounding , or processing of trade commodities and that can be said to be the
product of either innovation or substantial effort . There must be a direct relationship between the trade secret and the productive	<< 21 words >>	product of either innovation or substantial effort . There must be a direct relationship between the trade secret and the productive
Freedom of Information Act	<< 4 words >>	Freedom of Information Act
controls the public disclosure of previously unreleased information from federal	<< 10 words >>	controls the public disclosure of previously unreleased information from federal
each agency , upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published	<< 53 words >>	each agency , upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published

9864 words 29% matched		13089 words 21% matched
rules stating the time , place , fees (if any) , and procedures to be followed , shall make the records promptly available to any		rules stating the time , place , fees (if any) , and procedures to be followed , shall make the records promptly available to any
to make as much agency information available to the public as possible ,	<< 13 words >>	to make as much agency information available to the public as possible ,
information that is " exempted from disclosure by statute. "	<< 10 words >>	information that is " exempted from disclosure by statute. "
trade secrets and commercial or financial information obtained from a person and privileged or confidential ,	<< 16 words >>	trade secrets and commercial or financial information obtained from a person and privileged or confidential ,
reasonably details the information	<< 4 words >>	reasonably details the information
the confidentiality of requested information is	<< 6 words >>	the confidentiality of requested information is
uncertain , the FDA will contact the entity who submitted the information and/or who will	<< 15 words >>	uncertain , the FDA will contact the entity who submitted the information and/or who will
be affected by its disclosure before determining	<< 7 words >>	be affected by its disclosure before determining
whether to disclose the	<< 4 words >>	whether to disclose the

9864 words 29% matched		13089 words 21% matched
constitutes final agency action that is subject to judicial	<< 9 words >>	constitutes final agency action that is subject to judicial
If the affected person fails to intervene to defend the exempt status of the records	<< 15 words >>	If the affected person fails to intervene to defend the exempt status of the records
the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public	<< 35 words >>	the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public
the FDA ' s	<< 4 words >>	the FDA ' s
both the common law right of public	<< 7 words >>	both the common law right of public
pose additional threats for generic manufacturers who wish to protect their trade secrets .	<< 14 words >>	pose additional threats for generic manufacturers who wish to protect their trade secrets .
The common law right of public access	<< 7 words >>	The common law right of public access
to maintain open records of judicial proceedings .	<< 8 words >>	to maintain open records of judicial proceedings .
Nycomed US , Inc. v. Glenmark Generics , Inc. ,	<< 10 words >>	Nycomed US , Inc. v. Glenmark Generics , Inc. ,

9864 words 29% matched		13089 words 21% matched
Second Circuit declared in Lugosh v. Pyramid Co. of Onondaga ,	<< 11 words >>	Second Circuit declared in Lugosh v. Pyramid Co. of Onondaga ,
judicial documents are presumed to be open to public access	<< 10 words >>	judicial documents are presumed to be open to public access
In Stern v. Cosby , the Second Circuit	<< 8 words >>	In Stern v. Cosby , the Second Circuit
a three-part test to	<< 4 words >>	a three-part test to
the common law right of public	<< 6 words >>	the common law right of public
First , the court must determine whether the documents are indeed judicial documents	<< 13 words >>	First , the court must determine whether the documents are indeed judicial documents
Second , if the documents are judicial documents , the court must determine the weight of the presumption [of disclosure] . . . . Third , once the weight of the presumption is determined , a court must balance competing considerations against	<< 44 words >>	Second , if the documents are judicial documents , the court must determine the weight of the presumption [of disclosure] . . . . Third , once the weight of the presumption is determined , a court must balance competing considerations against
whether the documents were judicial documents to which the public had a right of access	<< 15 words >>	whether the documents were judicial documents to which the public had a right of access

9864 words 29% matched		13089 words 21% matched
end the inquiry here . The definition of	<< 8 words >>	end the inquiry here . The definition of
as discussed in Part	<< 4 words >>	as discussed in Part
relevant documents which are submitted to , and accepted by , a court of competent jurisdiction in the course of adjudicatory proceedings , [and] become documents to which the presumption of public access	<< 35 words >>	relevant documents which are submitted to , and accepted by , a court of competent jurisdiction in the course of adjudicatory proceedings , [and] become documents to which the presumption of public access
the documents with the relevant trade secret information	<< 8 words >>	the documents with the relevant trade secret information
unless the lawsuit concerns the	<< 5 words >>	unless the lawsuit concerns the
itself . In addition , even if a court does request documents containing trade secrets , generic manufacturers could argue against disclosure based on the theory behind the common law right itself . For example , if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected , then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court	<< 86 words >>	itself . In addition , even if a court does request documents containing trade secrets , generic manufacturers could argue against disclosure based on the theory behind the common law right itself . For example , if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected , then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court
reputation . Inventors , manufacturers , and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks .	<< 37 words >>	reputation . Inventors , manufacturers , and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks .

9864 words 29% matched		13089 words 21% matched
the weight of the presumption of disclosure ,	<< 8 words >>	the weight of the presumption of disclosure ,
a strong argument against disclosure . As the court notes ,	<< 11 words >>	a strong argument against disclosure . As the court notes ,
[T] he weight of the presumption depends on the	<< 11 words >>	[T] he weight of the presumption depends on the
of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal	<< 25 words >>	of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal
the high value of a	<< 5 words >>	the high value of a
being kept a secret from	<< 5 words >>	being kept a secret from
the presumption of disclosure by the court	<< 7 words >>	the presumption of disclosure by the court
the inquiry is often based largely on whether the information sought to be disclosed	<< 14 words >>	the inquiry is often based largely on whether the information sought to be disclosed
used for a motion to	<< 5 words >>	used for a motion to

9864 words 29% matched		13089 words 21% matched
Thus , for the purposes of a	<< 7 words >>	Thus , for the purposes of a
, unless the test itself was of central importance to the litigation , the presumption would weigh in favor of	<< 20 words >>	, unless the test itself was of central importance to the litigation , the presumption would weigh in favor of
the purpose of the doctrine ,	<< 6 words >>	the purpose of the doctrine ,
related to a motion to dismiss , because if the court dismisses a case based on a motion , it needs to show good cause for the dismissal . Finally ,	<< 31 words >>	related to a motion to dismiss , because if the court dismisses a case based on a motion , it needs to show good cause for the dismissal . Finally ,
manufacturer would be able to win the battle over disclosure at this step , if they could not do so via steps one or two . As	<< 27 words >>	manufacturer would be able to win the battle over disclosure at this step , if they could not do so via steps one or two . As
lucrative , competition-driving methods and formulas to the public during litigation ,	<< 12 words >>	lucrative , competition-driving methods and formulas to the public during litigation ,
active and vigorous defense of a trade secret is itself evidence of its value	<< 14 words >>	active and vigorous defense of a trade secret is itself evidence of its value
via the common law right of public access	<< 8 words >>	via the common law right of public access
causes the generic manufacturer to lose its competitive advantage , as well as the millions of dollars it invested in development of the	<< 23 words >>	causes the generic manufacturer to lose its competitive advantage , as well as the millions of dollars it invested in development of the

9864 words 29% matched		13089 words 21% matched
the presumption would favor disclosure . As demonstrated in Momenta ,	<< 11 words >>	the presumption would favor disclosure . As demonstrated in Momenta ,
offer a competitive advantage to generic companies who develop	<< 9 words >>	offer a competitive advantage to generic companies who develop
, the defendant sought to have the plaintiff ' s brief containing motions to amend the pleadings exempted from the common law right of public access , as the brief allegedly contained information that the defendant considered	<< 37 words >>	, the defendant sought to have the plaintiff ' s brief containing motions to amend the pleadings exempted from the common law right of public access , as the brief allegedly contained information that the defendant considered
argued that because two paragraphs of the plaintiff ' s motion contained *confidential information related to*	<< 16 words >>	argued that because two paragraphs of the plaintiff ' s motion contained confidential information related to
' s ANDA , this information was exempt from public	<< 10 words >>	' s ANDA , this information was exempt from public
The court , however , disagreed . This situation is	<< 10 words >>	The court , however , disagreed . This situation is
in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a	<< 24 words >>	in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a
protected via trade secret law , because information protected as trade secret would not be found in an opposing party	<< 20 words >>	protected via trade secret law , because information protected as trade secret would not be found in an opposing party

9864 words 29% matched		13089 words 21% matched
brief to start with , if it was actually a secret .	<< 12 words >>	brief to start with , if it was actually a secret .
In Nycomed , the defendant sought to protect information contained in the plaintiff	<< 13 words >>	In Nycomed , the defendant sought to protect information contained in the plaintiff
motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place	<< 20 words >>	motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place
if the alleged trade secret were really a secret .	<< 10 words >>	if the alleged trade secret were really a secret .
relevant provisions regarding the disclosure of pending ANDA	<< 8 words >>	relevant provisions regarding the disclosure of pending ANDA
Certainly , any information that is already public , or is independently made public , can not be deemed	<< 19 words >>	Certainly , any information that is already public , or is independently made public , can not be deemed
regulations guarded only against disclosure by the FDA and not the common law right of public	<< 16 words >>	regulations guarded only against disclosure by the FDA and not the common law right of public
, the presumption against disclosure during litigation should	<< 8 words >>	, the presumption against disclosure during litigation should
cut in favor of the generic manufacturer	<< 7 words >>	cut in favor of the generic manufacturer

9864 words 29% matched		13089 words 21% matched
In addition to the potential for disclosure due to a	<< 10 words >>	In addition to the potential for disclosure due to a
assertion of the common law doctrine of public access during litigation , the discovery rules could also pose a legitimate threat to	<< 22 words >>	assertion of the common law doctrine of public access during litigation , the discovery rules could also pose a legitimate threat to
manufacturers who seek to protect their	<< 6 words >>	manufacturers who seek to protect their
. As several cases have noted , there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil	<< 24 words >>	. As several cases have noted , there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil
However , many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during	<< 18 words >>	However , many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during
Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss	<< 13 words >>	Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss
and often work together to protect parties from	<< 8 words >>	and often work together to protect parties from
In Massey Coal Services , Inc. ,	<< 7 words >>	In Massey Coal Services , Inc. ,
issue a protective order pursuant to Rule 26 (c) (1) (G) to prevent a party from having to disclose a trade secret during the discovery stage of	<< 33 words >>	issue a protective order pursuant to Rule 26 (c) (1) (G) to prevent a party from having to disclose a trade secret during the discovery stage of

9864 words 29% matched		13089 words 21% matched
The plaintiff , Massey Coal , sued defendant , Victaulic , for various counts of breach of contract and	<< 19 words >>	The plaintiff , Massey Coal , sued defendant , Victaulic , for various counts of breach of contract and
defendants manufactured and installed piping that the plaintiff used in its	<< 11 words >>	defendants manufactured and installed piping that the plaintiff used in its
; when the pipes failed , the defendants admitted there was a problem but would not provide further	<< 18 words >>	; when the pipes failed , the defendants admitted there was a problem but would not provide further
Before the hearing , the judge issued a protective order for	<< 11 words >>	Before the hearing , the judge issued a protective order for
documents or other materials	<< 4 words >>	documents or other materials
[that are] confidential and should not be disclosed other than in connection with this	<< 16 words >>	[that are] confidential and should not be disclosed other than in connection with this
to the plaintiffs several documents marked	<< 6 words >>	to the plaintiffs several documents marked
of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail .	<< 23 words >>	of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail .
the pipes were used to carry drinking water throughout the county , the plaintiffs made a motion to disclose the information to the Public Service	<< 25 words >>	the pipes were used to carry drinking water throughout the county , the plaintiffs made a motion to disclose the information to the Public Service

9864 words 29% matched		13089 words 21% matched
The defendant objected , invoking protection from Rule 26 (c) (1) (G)	<< 18 words >>	The defendant objected , invoking protection from Rule 26 (c) (1) (G)
and arguing that the documents contained commercially valuable	<< 8 words >>	and arguing that the documents contained commercially valuable
For the purposes of analysis , the court noted that Rule 26 (c) (1)	<< 18 words >>	For the purposes of analysis , the court noted that Rule 26 (c) (1)
treats equally a trade secret or other confidential commercial	<< 9 words >>	treats equally a trade secret or other confidential commercial
Ultimately , the trial judge held that the documents were not protectable via Rule 26 (c) (1)	<< 21 words >>	Ultimately , the trial judge held that the documents were not protectable via Rule 26 (c) (1)
but the reasoning of the court	<< 6 words >>	but the reasoning of the court
in understanding the scope of the protection offered under 26 (c) (1) .	<< 17 words >>	in understanding the scope of the protection offered under 26 (c) (1) .
order to get a protective order for discovered documents under 26 (c) (1) , the party possessing the documents must show	<< 25 words >>	order to get a protective order for discovered documents under 26 (c) (1) , the party possessing the documents must show
for protection , including , most relevantly ,	<< 8 words >>	for protection , including , most relevantly ,

9864 words 29% matched		13089 words 21% matched
, the defendants in this case argued that	<< 8 words >>	, the defendants in this case argued that
Broad allegations of harm , unsubstantiated by specific examples	<< 9 words >>	Broad allegations of harm , unsubstantiated by specific examples
do not satisfy the Rule 26 (c) test . Moreover , the harm must be significant , not a mere	<< 22 words >>	do not satisfy the Rule 26 (c) test . Moreover , the harm must be significant , not a mere
Additionally , the court	<< 4 words >>	Additionally , the court
file a motion to seal the	<< 6 words >>	file a motion to seal the
, the court reasoned that the documents	<< 7 words >>	, the court reasoned that the documents
were not commercially valuable	<< 4 words >>	were not commercially valuable
that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants , the embarrassment was not a concern of the court and would not protect the documents from	<< 37 words >>	that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants , the embarrassment was not a concern of the court and would not protect the documents from

9864 words 29% matched		13089 words 21% matched
via trade secret law wishes to prevent disclosure via Rule 26 (c) (1) , it must show	<< 21 words >>	via trade secret law wishes to prevent disclosure via Rule 26 (c) (1) , it must show
for a protective order by demonstrating	<< 6 words >>	for a protective order by demonstrating
should provide the court with	<< 5 words >>	should provide the court with
specific examples or articulated reasoning	<< 5 words >>	specific examples or articulated reasoning
that disclosure of the trade secret would cause substantial economic harm to the manufacturer . Further , the manufacturer should show that this harm will be significant , and	<< 29 words >>	that disclosure of the trade secret would cause substantial economic harm to the manufacturer . Further , the manufacturer should show that this harm will be significant , and
factors commonly used to measure secrecy	<< 6 words >>	factors commonly used to measure secrecy
. Such factors can include :	<< 6 words >>	. Such factors can include :
[T] he extent to which the information is known by employees and others involved in the business	<< 19 words >>	[T] he extent to which the information is known by employees and others involved in the business
the extent of measures taken by the business to guard the secrecy of the information	<< 15 words >>	the extent of measures taken by the business to guard the secrecy of the information

9864 words 29% matched		13089 words 21% matched
the value of the information to the business and to its competitors	<< 12 words >>	the value of the information to the business and to its competitors
and the amount of effort or money expended in developing the	<< 11 words >>	and the amount of effort or money expended in developing the
take substantial time , effort , and funding to create , they are critical to	<< 15 words >>	take substantial time , effort , and funding to create , they are critical to
of the Federal Rules of Civil	<< 6 words >>	of the Federal Rules of Civil
which governs subpoenas , could also benefit a	<< 8 words >>	which governs subpoenas , could also benefit a
manufacturer seeking to protect a	<< 5 words >>	manufacturer seeking to protect a
through trade secret law during litigation . A	<< 8 words >>	through trade secret law during litigation . A
trade secret will lose its value if disclosed ; given the	<< 11 words >>	trade secret will lose its value if disclosed ; given the
so that they can	<< 4 words >>	so that they can

9864 words 29% matched		13089 words 21% matched
demonstrate , if necessary , why a	<< 7 words >>	demonstrate , if necessary , why a
trade secret should not be disclosed . When determining whether	<< 10 words >>	trade secret should not be disclosed . When determining whether
to quash a subpoena that could potentially pose a threat of disclosure to a	<< 14 words >>	to quash a subpoena that could potentially pose a threat of disclosure to a
trade secret , the court will balance the burden of disclosure with the potential	<< 14 words >>	trade secret , the court will balance the burden of disclosure with the potential
Although there is also no per se protection for trade secrets under Rule 45 , it is likely that a	<< 20 words >>	Although there is also no per se protection for trade secrets under Rule 45 , it is likely that a
manufacturer would be able to withstand disclosure of a	<< 9 words >>	manufacturer would be able to withstand disclosure of a
in the event of a subpoena . For example , In re Fosamax	<< 13 words >>	in the event of a subpoena . For example , In re Fosamax
manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure . A group of plaintiffs sued	<< 24 words >>	manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure . A group of plaintiffs sued
defendant drug company , Merck & Co. , alleging that a drug they manufactured , Fosamax , caused adverse side	<< 20 words >>	defendant drug company , Merck & Co. , alleging that a drug they manufactured , Fosamax , caused adverse side

9864 words 29% matched		13089 words 21% matched
to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the	<< 22 words >>	to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the
moved to quash the subpoena under Rule 45 (d) (3) (B)	<< 17 words >>	moved to quash the subpoena under Rule 45 (d) (3) (B)
confidential information or trade	<< 4 words >>	confidential information or trade
the burden between necessity of the testimony and the undue burden on the defendant to produce the information	<< 18 words >>	the burden between necessity of the testimony and the undue burden on the defendant to produce the information
whether there is an undue burden on the defendant	<< 9 words >>	whether there is an undue burden on the defendant
the personal hardship to the party protecting the information	<< 9 words >>	the personal hardship to the party protecting the information
the wider social consequences of disclosing the	<< 7 words >>	the wider social consequences of disclosing the
Here , the court noted that if Dr. Psaty were required to testify ,	<< 14 words >>	Here , the court noted that if Dr. Psaty were required to testify ,
the resulting social impact would be far more serious . Compelling testimony from a	<< 14 words >>	the resulting social impact would be far more serious . Compelling testimony from a

9864 words 29% matched		13089 words 21% matched
researcher risks chilling participation in beneficial public	<< 7 words >>	researcher risks chilling participation in beneficial public
Thus , the court recognized the value of trade secrets , suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them .	<< 33 words >>	Thus , the court recognized the value of trade secrets , suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them .
be required to disclose	<< 4 words >>	be required to disclose
the burden between necessity of the testimony and the undue burden	<< 11 words >>	the burden between necessity of the testimony and the undue burden
personal hardship to the	<< 4 words >>	personal hardship to the
. Although trade secret law does not provide per se protection from	<< 12 words >>	. Although trade secret law does not provide per se protection from
manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests , FDA use of the information , and	<< 31 words >>	manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests , FDA use of the information , and
litigation . Although FOIA encourages the broad disclosure of	<< 9 words >>	litigation . Although FOIA encourages the broad disclosure of
manufacturer can demonstrate to the FDA	<< 6 words >>	manufacturer can demonstrate to the FDA

9864 words 29% matched		13089 words 21% matched
trade secrets are immune from disclosure . The	<< 8 words >>	trade secrets are immune from disclosure . The
manufacturer can point to the definition of trade secret adopted in Public Citizen Health to argue that	<< 17 words >>	manufacturer can point to the definition of trade secret adopted in Public Citizen Health to argue that
qualifies as a trade secret , exempting it from disclosure .	<< 11 words >>	qualifies as a trade secret , exempting it from disclosure .
protected information submitted to it by a third party under limited circumstances	<< 12 words >>	protected information submitted to it by a third party under limited circumstances
a trade secret , the threat of disclosure by the FDA is manageable . Finally ,	<< 16 words >>	a trade secret , the threat of disclosure by the FDA is manageable . Finally ,
the common law right of public access	<< 7 words >>	the common law right of public access
and discovery requests made by parties to a litigation , can also be overcome by	<< 15 words >>	and discovery requests made by parties to a litigation , can also be overcome by
test developed by the Second Circuit in Stern v. Cosby	<< 10 words >>	test developed by the Second Circuit in Stern v. Cosby
disclosure present in the common law right of public access can be avoided by	<< 14 words >>	disclosure present in the common law right of public access can be avoided by

9864 words 29% matched		13089 words 21% matched
as trade secrets . Furthermore ,	<< 6 words >>	as trade secrets . Furthermore ,
manufacturers could also protect their	<< 5 words >>	manufacturers could also protect their
trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45 .	<< 21 words >>	trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45 .
research and development investments from	<< 5 words >>	research and development investments from
the safe harbor provision of the Hatch Waxman	<< 8 words >>	the safe harbor provision of the Hatch Waxman
an effect confirmed by later	<< 5 words >>	an effect confirmed by later
In light of the Momenta holding	<< 6 words >>	In light of the Momenta holding
from use by their competitors	<< 5 words >>	from use by their competitors
a viable alternative to patent protection for	<< 7 words >>	a viable alternative to patent protection for

9864 words 29% matched		13089 words 21% matched
the threat of disclosure from	<< 5 words >>	the threat of disclosure from
the threat of disclosure	<< 4 words >>	the threat of disclosure
the FDA ' s own use of	<< 7 words >>	the FDA ' s own use of
test . Third , generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution , and that this purpose would be defeated if the court disclosed a manufacturer	<< 53 words >>	test . Third , generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution , and that this purpose would be defeated if the court disclosed a manufacturer
extremely valuable information to competitors . Finally ,	<< 8 words >>	extremely valuable information to competitors . Finally ,
by invoking Federal Rules of Civil Procedure 26 (c) against discovery requests for documents and Rule 45 against subpoenas .	<< 22 words >>	by invoking Federal Rules of Civil Procedure 26 (c) against discovery requests for documents and Rule 45 against subpoenas .
, trade secret law	<< 4 words >>	, trade secret law
alternative to patent protection for	<< 5 words >>	alternative to patent protection for

EXHIBIT E

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Emerging Issues in Litigation and Protections Regarding the Progressive Switch from Patent to Trade Secret Protections in the Biotech and Pharmaceutical Industry

By Trisha Tshudy

I. Introduction

The United States has the largest and fastest growing drug market in the world, and the demand for generic drugs and biologics is steadily growing. Each year the pharmaceutical industry invests millions of dollars in promoting the research and development of new and generic drugs. With biotech discovery comes the need for businesses to retain their competitive advantage and for legislation and the judicial system to provide methods of doing so. While most pharmaceutical drug manufacturers still rely on patent protection in some capacity, companies are slowly including trade secrets in combination or as replacements to protect their intellectual property. This paper aims to explain the issues biotech and pharmaceutical companies are encountering in patent law that is leading to this change in intellectual property protection. The issues include It then tackles what issues are arising for those companies in attempting to litigate trade secret cases in a judicial system that requires some level of disclosure.

IMPORTANT NOTE For the following discussion, research and development which includes aspects of testing and are often susceptible to these infringements constitute the patent eligible category called "process." The following discussion is in reference to these "process" patents, also known as method patents and refer to the refinement of the manufacturing process.

II. Emerging Issues in Patent Protection

Patent protection was effective when the greatest value was in the product instead of the process. With the success of the industry and its exponential growth in competition, patents have now become less of a deterrent and more of an encouragement of competitors to capitalize off the work of their competitors. As the industry changes to more complicated products such as biologics, reverse engineering becomes less of a concern than patent scope. Additionally, the success of pharmaceuticals means a continuous goal of

refinement and improvement exists for patented products. But once the cookie cutter patent is made, the inability to modify patents to extend protections to improvements to these methods is a deterrent to relying on patents when developing the best product. Patents are becoming a cookie cutter of protection in a pastry industry; they are failing to adapt. Lastly, As the pharmaceutical industry builds, its exponential growth means that the ability of competitors to repeat the processes is greatly increased. So, lack of patent protection for processes greatly weakens the value that they have. Beyond that, even judicial rulings weaken patent protections themselves.

A. The patent system's failure to adjust to product and method refinement and recognize the value of process is a key force behind the movement of manufacturers to the use of trade secrets as a patent alternative.

The inability for patents to be adjusted to continued improvements and refinements of products prevents pharmaceutical companies from protecting their desire to create the best product available for their consumers and weakens them to be overcome by competitors. Additionally, as the industry advances creating more complicated products, the need for greater protection for processes and tests is sorely lacking. Also, more advanced products consequently create more uncertainty and difficulty in product standardization that lead to patent invalidity.

Patents lack the ability to alter patent protections until exclusivity period lapses. As the industry advances, manufacturing facilities and processes require frequent reassessment to ensure production of safer, more pure, more stable, and more potent products. Unfortunately, the patent and drug regulatory law traditionally utilized by manufacturers to protect their investments and simultaneously signal where innovation and investment are severely lacking. The manufacturer can either disclose critical aspects of the process in return for patent exclusivity periods or withhold information as trade secrets to prevent follow-on manufacturers from reverse-engineering their processes. A manufacturer should not feel restricted to wait until their exclusivity period lapses for them to obtain a higher degree of process control. The manufacturer

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ideally wants the patent to be broad enough to protect subsequent innovation, while narrow enough to prevent subsequent biopharmaceutical manufacturers from reverse-engineering and pushing the biologic originator out of the market. [1] Yet competitors still capitalize on these abbreviated approval pathways.[2] As a result, significant opportunity exists in the regulatory framework to incentivize the research and development of manufacturing processes.

While some companies in the industry are advocating for data exclusivity extensions, the FDA's failure to regularly grant market exclusivity privileges for manufacturing process improvements alone has led companies to rely on trade secrets to fill the void. The issue of scope in the context of biopharmaceutical and biotech research arises in numerous and often conflicting situations. One such issue is whether these discoveries should be allowed the dual protection of both product and process patents,[3] which may overly broaden their scope.[4] Merges and Nelson submit that it is the process, rather than the product, which the inventor discovered. [4] The discovery of a new use for an existing product does not currently fit within patent protections, but some argue it should be awarded a process patent. [5] Other common discoveries such as those that improve the purity of a substance or to find a way to decrease the production costs by inventing synthetic versions of natural substances are considered by some to be double patenting and thus, should not be allowed.[5] In In re Wands, the Federal Circuit held that to claim a process, one must enable all the elements and components to perform such a process. This prevents inventors from patenting both the process and the product itself. [6] These data exclusivity grants are effectively like the very exclusionary right in patent law that Congress felt blocked competition and created artificial scarcity enough to create the Hatch Waxman safe harbor provision that is addressed in a more comprehensive assessment about alterations in patent scope leading to a rise in trade secret reliance. Beyond implementation issues, we will then take a look at how variations in scope a significant factor in the movement toward trade secret dependency are also.

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B. Variations in patent scope are an additional cause for manufacturers to move to trade secret dependency.

As mentioned above, decrease in patent dependence represents a culmination of issues with patents such as increased complication of patent standards, lack of patent validity insurance, antitrust ruling eliminating financial alternatives to prevent validity litigation, dual patenting (product and process) discouragement, additional trade secret protections. Originally, federal legislation greatly favored and offered extended protection to patents over trade secrets. Patents were regulated directly through the Federal Food, Drug, and Cosmetics Act [7] and the Drug Price Competition and Patent Term Restoration Act of 1984 (the ***Hatch-Waxman*** Act), [8] and indirectly through regulations promulgated by the Food and Drug Administration (FDA). [9] Despite these protections, patent law is progressively weakening. The increasingly complicated nature of patent formation leads companies to be concerned about their standing and therefore, desire to protect it from litigation, but in a recent case, even that alternative was removed as an option.

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Recent judicial decisions have weakened the protections garnered by patents. One such example is the expansion of the scope of the safe harbor provision of the Hatch-Waxman Act that allows competing drug manufacturers to "borrow" information within the patents of their competitors if it was specifically for the purpose of their own FDA submission. In the 2012 case *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* [10] the Federal Circuit held that via the safe harbor provision, competing generic pharmaceutical manufacturers could use each other's patented testing methods for pre-clinical research and manufacturing without incurring infringement liability. Although Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA) litigation not only gave its competitor use of Amphastar's testing method to develop its own generic, but the litigation delay also gave the competitions generic a year to monopolize the product resulting in profits over $260 million.[10] Thus, the Federal Circuit's holding in *Momenta* threatens manufacturers of generics with a devastating loss of previously available patent protection for testing methods. *Momenta* demonstrates that the scope of the safe

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harbor provision has been expanded to such an extent that protection via method patents is no longer available.

Beyond rulings that weaken or eliminate the options of method or process protections through patents, rulings have also shown granted patents may be ultimately invalidated or temporarily invalidated leading to drastic consequences for the companies that worked so hard to obtain them. In *Pfizer v. Apotex*, the plaintiff patentee was granted a judgment of infringement and injunctive relief against the defendant which manufactured a generic version of the patentee's drug Norvasc before the expiration of the term of the patent. On appeal, the generic manufacturer challenged the ruling that the patent was not invalid for obviousness. The original drug was developed with a different salt of the key ingredient, amlodipine, but the patentee determined that use of a besylate salt was superior. The generic manufacturer certified that it believed the patent was invalid and unenforceable. If the patent was upheld as valid, the product would literally infringe the claims. The district court rejected the argument that the prior art rendered the invention of the claims of obviousness. On appeal, the court found the evidence of record easily shown by clear and convincing evidence that a skilled artisan would in fact have been motivated to combine the prior art to produce the specified compound. The court declared that it would have been obvious to one skilled in the art to make amlodipine besylate. That the patentee had to verify through testing the expected traits of each acid addition salt was of no consequence. The judgment of the district court was reversed because the subject matter of the patent claims in issue would have been obvious. Ultimately, the determination is one of weight and totality of the evidence. According to the Graham Test, the weight given to the patent examiner's determination should constitute only on factual consideration in a court's consideration of the totality of the circumstances. As wonderful as bright line rules are, the variability of individual cases often require this totality of the circumstance's tests. I believe in this case it was very important because it is dangerous to rely on one person's testimony no matter their authority or specialization, so it's a good pattern to develop.

Patent's strength depends on their approval ensuring coverage. Trade Secrets do not go through the same official approval process, so they do not have the extra level of verification that they meet

the definition and qualify for the requisite protection. Unfortunately, patents have been successively limited not only in scope, but even effectively after approval. This increased recognition that patents are no longer guaranteed after verification and can later be ruled invalid has weakened one of their strongest advantages over trade secrets. Patent invalidity now represents a comparable weakness to companies' own responsibility to make sure their trade secrets meet the definition required for protections to apply.

As improper patent writing has led companies' patents to fail. Some companies attempted to circumvent litigation and rulings on the validity of their patents through agreements with the competition to respect those patents. In FTC vs. Actavis, the Supreme Court considered whether a "reverse payment" settlement agreement can sometimes unreasonably diminish competition in violation of antitrust laws. [11] For my own notation, the reverse payment agreement entails that in a situation where Company A sues Company B for patent infringement, the two companies settle on terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B millions of dollars. Requiring the patentee to pay the alleged infringer is what constitutes the reverse as well as introduces the antitrust issue of discouraging competition. The 11th Circuit believed that the only pertinent question was whether the settlement agreement falls within the legitimate scope of the patent's exclusionary potential. The Supreme Court disagreed with measuring the length or amount of restriction based solely against the length of the patent's term and earning potential, and instead considered traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances (patent litigation). Whether a restraint lies beyond the limits of patent monopoly is the conclusion from this analysis and not the starting point. The Court further explains that the price of payout can be a direct indicator of the patentee's confidence in the validity of their patent and that reverse payments are a strong indicator of higher-than competitive profits which is a strong indicator of market power. The Court explained that litigation is more feasible than believed because these cases don't require an assessment of patent liability, they would only require an antitrust analysis. At the same time, the Court refused to follow the FTC's

request that the presumption should be that these agreements are unlawful and should only receive a "quick-look" approach before ruling so. The Court ruled that the complexities of these cases require the FTC to prove its case just as in other rule-of-reason cases. Aside from the antitrust implications, this ruling effectively eliminated a possible alternative of companies to mitigate the challenges to patent validity currently plaguing the system.

Until Congress decides to narrow the scope of the Hatch-Waxman provision, the patent system allows for dual or process patents, and the patent system allows for updates to patents within their period of coverage for companies who prioritize patient care to improve their methods and products, the industry will likely continue to progress towards using trade secrets for their intellectual property protection. As trade secret litigation grows, so do the emerging issues in litigation. Fortunately, a solution exists for generic drug manufacturers who wish to shield their tests and methods from the hungry eyes of their competitors. Despite the numerous regulations governing disclosure of information submitted to the FDA, including most notably the Freedom of Information Act (FOIA), generic drug manufacturers, using a heightened degree of care, can protect their testing methods and processes as trade secrets.

III. Trade Secret Law and the Potential Threats of Disclosure

While patent protection and the judicial system in general relies on disclosure, the trade secret protection depends on the lack of it. Therefore, proper treatment of trade secrets during litigation has led to the emergence of unique issues. Those issues include the threat of disclosure from mis definition, requests via the freedom information act, FDA use, discovery requests and the common law right of public access. including reconsideration of notification standards and the process of discovery.

A. Proper Compliance with the Definitions of Trade Secrets

Trade secrets do not require registration to qualify for trade secret protection, but their protection still depends on their ability to meet the definition and fall under its scope. Because of the nature of the product, the biotech and pharmaceutical industry still needs to pass FDA standards to be approved for medical use.

While trade secret law originally evolved under state common law, the Uniform Trade Secrets Act (UTSA), [12] extended trade secret recognition across states. [13] The USTA provides a broad definition, defining a trade secret as "information, held by one or more people, without regard to form, including a formula . . . method . . . technique … or process that: (1) derives independent economic value … from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." [14] It is important to note that while this is the general definition under the act, each manufacturer should be mindful of state specificities that could affect the application and the scope of the trade secret protection within their state. [15] The FDA provides their own definition for trade secrets which should also be considered particularly when submitting ANDAs. [16] Similarly the FDA, defines a trade secret as, "[A]ny commercial valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." [17] Because disclosure is essential to maintenance of trade secret protection the FDA offers that they "will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information. Except where specifically exempt pursuant to the provisions of this part, all FDA records shall be made available for public disclosure." [18, 19] Based upon the emphasis of protection's dependency on definition throughout all these regulations, the courts have used these as input to develop their own definition to standardize the scope for litigation measures. The courts currently specify that, "A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process." [20] Given the consideration of the trade secret definitions provided by the UTSA, state regulations, and the FDA in conjunction with the commitment to protections of trade secrets by

each, the responsibility is therefore placed in the business' hands to ensure their own compliance to definition.

B. Information Requests Via the Freedom of Information Act and the FDA's General Disclosure Policy

One example of the importance of proper compliance with these definitions is to empower these sources of protections to withstand the common law right of public access and even specific inquiries under the Freedom of Information Act (FOIA). The Freedom of Information Act controls the public disclosure of previously unreleased information from federal agencies and coincides with common law right of public access. [21] Specific requests can be made under the act for information that was required for FDA approval as well as information recognized within litigation. [22, 23, 24] Concerningly, section 3 of the FOIA that with few exceptions, "each agency, upon *any* request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, *shall* make the records promptly available to any person. [25] Additionally it requires the agency to perform reasonable searches for the information [26] and its findings in the format requested. [27]

While the FOIA aims to make as much agency information available to the public as possible, one of their few strict exemptions includes information that is "exempted from disclosure by statute." [28] if the statute is clear of its scope and cites to the FOIA. [29, 30] Additionally the FOIA does specify an exemption for "trade secrets and commercial or financial information obtained from a person and privileged or confidential," [31] without prior implementation in case law, manufacturers cannot be certain whether their information fits the scope of protection. This means that even a request submitted by competitors that reasonably details the information desired could lead the FDA to disclose valuable competitor information. [32] Fortunately, if the confidentiality of requested information is unknown or uncertain, the FDA will contact the entity who submitted the information and/or who will "be affected by its disclosure before determining" whether to disclose the information. [33] Any FDA rejection of a FOIA request "constitutes final agency

action that is subject to judicial review" [34] and the entity requesting the information has five days after notice to file suit. [35]. If a suit is filed, the person who declared confidentiality will be required to defend their claim in court. [36]. The ruling statute reads, "If the affected person fails to intervene to defend the exempt status of the records … the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public disclosure." [36] While the defense is not mandatory, it weighs heavily on the FDA's determination of disclosure. [36] If proper compliance with the definition causes an FOIA request to be limited or rejected, the competitor can also pursue disclosure through both the common law right of public access [37] and discovery request [38] pose additional threats for generic manufacturers who wish to protect their trade secrets.

C. Right of Public Access

The common law right of public access places trade secrets in direct contention with the court's desire to maintain open records of judicial proceedings. In *Nycomed US, Inc. v. Glenmark Generics, Inc.*, the Second Circuit emphasized the importance of public access to maintain an appearance of judicial legitimacy. [39] The Second Circuit declared in *Lugosh v. Pyramid Co. of Onondaga*, that judicial documents are presumed to be open to public access. [40] This presumption places the burden on trade secret confidentiality on the manufacturers. In *Stern v. Cosby*, the Second Circuit determined a three-part test to be applied to trade secret cases where a judicial document may fall under the common law right of public disclosure. [41] "First, the court must determine whether the documents are indeed judicial documents … Second, if the documents are judicial documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it." [42] The three-part test is an additional standard that, coupled with the general right to access, represents emerging issues in litigation that threatens the disclosure of trade secrets. Fortunately, the uniquely disclosure dependent nature of biotech trade secrecy means that the value of confidentiality tends to be weighed above the value of necessary public disclosure requirements. [43]

The first factor considers "whether the documents were judicial documents to which the public had a right of access." [44]Properly presented, the manufacturer could possibly end the inquiry here. The definition of "judicial documents," as discussed in Part II.C, [45] is "relevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings, [and] become documents to which the presumption of public access applies." [46] Therefore, the documents with the relevant trade secret information must be requested or submitted by the court in order for the definition to apply. The necessity of inclusion is unlikely unless the lawsuit concerns the method contained within the trade secret itself.

In addition, even if a court does request documents containing trade secrets, generic manufacturers could argue against disclosure based on the theory behind the common law right itself. For example, if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected, then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court's reputation. Inventors, manufacturers, and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks.

The second factor, "the weight of the presumption of disclosure," [47] would again, if properly presented, represent a strong argument against disclosure. As the court notes, "[T]he weight of the presumption depends on the 'role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal courts.' " [48] Therefore, the high value of a method being kept a secret from competitors would lessen the presumption of disclosure by the court and would weigh in favor the biotech manufacturers position. Additionally, the court finds that the inquiry is often based largely on whether the information sought to be disclosed essential to the litigation. The strongest evaluation of this is if the information can be used for a motion to dismiss. [48] Thus, for the purposes of a biotech manufacturer protecting a method, unless the test itself was of central importance to the litigation, the presumption would weigh in favor of nondisclosure.[48] Additionally, considering the

purpose of the doctrine, the presumption is logically stronger for information directly related to a motion to dismiss, because if the court dismisses a case based on a motion, it needs to show good cause for the dismissal.

Finally, the third factor, competing considerations against the presumption, [48] would again increase the likelihood that a biotech manufacturer would be able to win the battle over disclosure at this step, if they could not do so via steps one or two. As previously mentioned, courts' disclosure of lucrative, competition-driving methods and formulas to the public during litigation, will deter biotech manufacturers who desire protection from seeking it through judicial remedies. A manufacturer's active and vigorous defense of a trade secret is itself evidence of its value in the same way as its prerequisite investments to prevent disclosure are as well. The third factor directly corresponds to the same issue of litigation that deterred manufacturers from the use of patents for protection mentioned previously. Even if public disclosure occurs via the common law right of public access, it still causes the generic manufacturer to lose its competitive advantage, as well as the millions of dollars it invested in development of the secret. [49] Therefore, the presumption would favor disclosure. As demonstrated in *Momenta*, processes and methods offer a competitive advantage to generic companies who develop them, and their protection is essential to maintaining the value that incentivizes the industry overall. [49] Derogation of this incentive would cause adverse repercussions to the industry and society.

In *Nycomed*, we observe such an example. Here, the defendant sought to have the plaintiff's brief containing motions to amend the pleadings exempted from the common law right of public access, as the brief allegedly contained information that the defendant considered confidential. [50] The defendant argued that because two paragraphs of the plaintiff's motion contained confidential information related to the defendant's ANDA, this information was exempt from public disclosure. [50] The court, however, disagreed. This situation is distinguishable from one in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a method protected via trade secret law, because information protected as trade secret would not be found in an opposing party's brief to start with, if

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it was actually a secret. It is the very element of unique and unknown qualities trade secrets necessitate. In *Nycomed*, the defendant sought to protect information contained in the plaintiff's brief. If the trade secret is correctly maintained, then it's only logical that an opposing party's motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place if the alleged trade secret were really a secret. The court reviewed the FDA's relevant provisions regarding the disclosure of pending ANDA's before noting that, "Certainly, any information that is already public, or is independently made public, cannot be deemed confidential." [50] Additionally the court mentioned that the FDA's regulations guarded only against disclosure by the FDA and not the common law right of public access. [50] Therefore, the presumption against disclosure during litigation should be cut in favor of the generic manufacturer if the generic manufacturer treats the method information allegedly within the scope of the common law right of public access as a legitimate secret.

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D. Notice Requirements and Discovery Requests

In addition to the potential for disclosure due to a competitor's assertion of the common law doctrine of public access during litigation, the discovery rules could also pose a legitimate threat to biotech manufacturers who seek to protect their methods. As several cases have noted, there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil Procedure. [54] However, many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during discovery. [55] Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss 'trade secrets,' [56] and often work together to protect parties from disclosure. [57]

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As mentioned, notice requirements and discovery requests also pose a threat to manufacturers who choose to protect their methods via trade secrets. The Federal Rules of Civil Procedure do not contain an absolute privilege for trade secrets that are requested during discovery or required during pleading to prevent summary judgment. [51] Despite this, Rules 26 and 45 are a potential avenue for biotech manufacturers to protect their method trade secrets from disclosure during these crucial steps in litigation. One such means is

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through protective order. Rule 26 outlines a way in which a party may receive such a protective order from the court to guard against the disclosure of a trade secret [52]: "The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action." [52] Additionally, the rule states, "the court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" by several following methods. [52] One such method includes: "requiring that a trade secret or other confidential research development, or commercial information not be revealed or be revealed only in a specific way." [53] Although there is no *per se* protection of trade secrets in the Federal Rules of Civil Procedure, if the party seeking protection accepts the burden of proof and argues that the information should not be disclosed via Rule 26 and should be granted a protective order, the avenue of protection is maintained.

In *Massey Coal Services, Inc.*, the court elaborated on which circumstances would allow a court to issue a protective order pursuant to Rule 26(c)(1)(G) to prevent a party from having to disclose a trade secret during the discovery stage of litigation. [58] The plaintiff, Massey Coal, sued defendant, Victaulic, for various counts of breach of contract and misrepresentation. [58] According to the claim, the defendants manufactured and installed piping that the plaintiff used in its coal mines; when the pipes failed, the defendants admitted there was a problem but would not provide further information. [58] Before the hearing, the judge issued a protective order for "documents or other materials … subject to disclosure … [that are] confidential and should not be disclosed other than in connection with this action." [58] Pursuant to the protective order the defendant proceeded to disclose to the plaintiffs several documents marked 'CONFIDENTIAL', several of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail. Since the pipes were used to carry drinking water throughout the county, the plaintiffs made a motion to disclose the information to the Public Service Authority. [58] The defendant objected, invoking protection from Rule 26(c)(1)(G) [58] and arguing that the documents contained

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commercially valuable information. [58] For the purposes of analysis, the court noted that Rule 26(c)(1) "treats equally a trade secret or other confidential commercial information."

Ultimately, the trial judge held that the documents were not protectable via Rule 26(c)(1), [58] but the reasoning of the court indicated crucial aspects of consideration for circumstances that would allow the opposite finding including instances that did not represent a public safety concern. Overall, the courts analysis is extremely valuable in understanding the scope of the protection offered under 26(c)(1). Accordingly, in order to get a protective order for discovered documents under 26(c)(1), the party possessing the documents must show "good cause" for protection, including, most relevantly, "undue burden or expense." [59] In other words, the defendants in this case argued that good cause was in the "severe economic damage" prevented by avoiding disclosure.[60] The court noted, "Broad allegations of harm, unsubstantiated by specific examples … do not satisfy the Rule 26(c) test. Moreover, the harm must be significant, not a mere trifle." [60] Additionally, the court recognized that defendants did not show full compliance with the trade secret standard because they failed to present any evidence that specific efforts were made to maintain the trade secrets, [60] object to disclosure of the documents to the plaintiffs, consider that the documents were contained in the court's public record, or failed to file a motion to seal the documents. [60] Therefore, the court reasoned that the documents were not compliant with trade secret standards and thus were not commercially valuable or protectable. [60] The trial judge specifically mentioned that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants, the embarrassment was not a concern of the court and would not protect the documents from disclosure. [60]

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The *Massey* court's holding and reasoning showed that if a biotech manufacturer protecting a method via trade secret law wishes to prevent disclosure via Rule 26(c)(1), it must show "good cause" for a protective order by demonstrating "undue burden or expense." [61] Additionally, the biotech manufacturer must argue and present evidence that meets a certain level of specificity. In other words, they should provide the court with "specific examples or articulated reasoning" [62] to show that disclosure of the trade secret

would cause substantial economic harm to the manufacturer. Further, the manufacturer should show that this harm will be significant, and "not a mere trifle." [62] The Restatement of Torts provides some valuable factors commonly used to measure secrecy that would be a valuable resource towards meeting this standard. Such factors can include:

"[T]he extent to which the information is known by employees and others involved in the business … the extent of measures taken by the business to guard the secrecy of the information … the value of the information to the business and to its competitors … and the amount of effort or money expended in developing the information." [63]

Again, since methods take substantial time, effort, and funding to create, they are critical to any biotech manufacturer's market competitiveness and often represent greater value than the product itself because of their ability to apply to multiple products. [64] This increased value should heighten the importance of their protection. Biotech manufacturers should therefore heighten their consideration and implement higher measures and care to maintain their secrecy. Steps such as increase technological security, restriction of employee access, restriction of employees to specific subject matter, confidentiality agreements or noncompete agreements are just a few ways that can not only ensure greater protection of the trade secrets in general, but also incur a greater weight to the value of the trade secrets when it comes to the consideration by the courts. The more investments taken, the more value represented and the increased likelihood that privilege and confidentiality can be established allowing for greater protection throughout litigation.

E. Subpoenas

While Rule 26 combats general disclosure, Rule 45 is considered a way to prevent wrongful disclosure during discovery by protecting trade secrets from subpoenas. Rule 45 states, "To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information … " [65] In subsequent case law where a court is deciding whether to

quash a subpoena which seeks information marked as a trade secret, "a court must evaluate all the circumstances and balance, inter alia, the requesting party's need for the information and the potential prejudice imposed on the requested party." [66] The court also considers "the relevance of the discovery sought, the requesting party's need, and the potential hardship to the party subject to the subpoena." [67]

In addition, Rule 45 of the Federal Rules of Civil Procedure, [68] which governs subpoenas, could also benefit a biotech manufacturer seeking to protect a method through trade secret law during litigation. A manufacturer's trade secret will lose its value if disclosed; given the increased value of biotech methods currently observed in the industry, biotech manufacturers should understand the risks attributed to potential subpoenas so that they can preemptively prepare for the potential need to demonstrate, if necessary, why a method trade secret should not be disclosed. When determining whether to quash a subpoena that could potentially pose a threat of disclosure to a manufacturer's method trade secret, the court will balance the burden of disclosure with the potential need for the information argued in litigation. [69]

Although there is also no *per se* protection for trade secrets under Rule 45, it is likely that a manufacturer would be able to withstand disclosure of a method in the event of a subpoena. For example, *In re Fosamax* demonstrated that biotech manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure. A group of plaintiffs sued the defendant drug company, *Merck & Co.*, alleging that a drug they manufactured, Fosamax, caused adverse side effects.[70] The court issued a subpoena at the behest of the plaintiffs to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the guidance of the FDA.[70] Dr. Psaty stated that he never studied the drug in question and moved to quash the subpoena under Rule 45(d)(3)(B).[70] [71] Additionally, the defendant argued that allowing Dr. Psaty testimony was an uncertain and unnecessary risk to the potential disclosure of confidential information or trade secrets.[71] In response, the court balanced the burden between necessity of the testimony and the undue burden on the defendant to produce the information and ultimately quashed the subpoena. [71] The court further considered whether there is an undue burden on the defendant and assessed the personal hardship to the party protecting the information as well as

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the wider social consequences of disclosing the information. [71] Here, the court noted that if Dr. Psaty were required to testify, "the resulting social impact would be far more serious. Compelling testimony from a third-party researcher risks chilling participation in beneficial public research." [71] Thus, the court recognized the value of trade secrets, suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them.

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When comparing this case with the potential disclosure of a biotech manufacturer's method, manufacturers who receive subpoenas would rarely if ever be required to disclose trade secrets if called to testify. Even if the testimony sought had important implications to the case's subject matter or overall determination, the balancing of the burden between necessity of the testimony and the undue burden placed on the defendant would likely weigh in favor of quashing the subpoena. The personal hardship to the individual biotech manufacturer would be catastrophic, resulting in the loss of millions of dollars in profits or the loss of commercial market advantage and the industry would undergo similar repercussions to the rulings that led to the deterrence of trade secret use already discussed. [72] This time, possibly more severe without an alternative option currently in existence for biotech manufacturers to turn to. In addition, requiring biotech manufacturers to disclose trade secrets would not only have a chilling effect on beneficial scientific research and disincentivizing the investment, but could also have a much wider social impact that would weigh in favor of suppressing the subpoena for risk of unforeseen consequences.

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Although trade secret law does not provide per se protection from disclosure, [73] biotech manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests, FDA use of the information, and the notice requirements, discovery, and public right to information emerging from litigation. Although FOIA encourages the broad disclosure of information obtained by a government agency or judicial body, a biotech manufacturer can demonstrate to the FDA's FOIA office that method trade secrets are immune from disclosure. The biotech manufacturer can point to the definition of trade secret adopted in Public Citizen Health to argue that the information qualifies as a trade secret, exempting it from disclosure. The FDA's

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restriction to only disclosing protected information submitted to it by a third party under limited circumstances, provides biotech manufacturers with an avenue to combat the threat of disclosure from the FDA's one potential use. If the FDA recognizes that their power of disclosure is limited by and weighed against the property interest biotech manufacturers hold in their method trade secrets, and as long as biotech manufacturers properly comply with the FDA qualification standards for what constitutes a trade secret, the threat of disclosure by the FDA is manageable. Finally, threats of disclosure and emerging litigation issues, such as the common law right of public access, notice requirements, and discovery requests made by parties to a litigation, can also be overcome by biotech manufacturers in the ways outlined. The three-part test developed by the Second Circuit in *Stern v. Cosby* demonstrates that the judicial system's presumption favoring disclosure present in the common law right of public access can be avoided by biotech manufacturers protecting methods as trade secrets. Furthermore, biotech manufacturers could also protect their method trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45. Therefore, these avenues demonstrate that despite the emerging issues in the use of trade secrets over patent protection, biotech manufacturers could successfully rely on trade secrets to protect their research and development investments from competitors in ways patent law has not yet allowed.

IV. Conclusion

In summation, as argued by the dissent in Momenta that holdings and similar ones have used the safe harbor provision of the Hatch Waxman Act to render all patents on testing methods worthless, [74] an effect confirmed by later proceedings. [75] In light of the Momenta holding and other noted cases, opportunities for manufacturers to protect their intellectual property that constitutes methods or processes from use by their competitors has been removed from patent law. Fortunately, recently federalized protections for trade secrets are proving to be a viable alternative to patent protection for biotech and pharmaceutical manufacturers until Congress decides to act against these dangerous precedents. Therefore, biotech

manufacturers' increased dependence employs greater understanding and resolution of the issues that trade secret reliance has identified.

These emerging issues include the threat of disclosure from FOIA requests that can be prevented by proper compliance with the definitions set forth by statute and agencies, the threat of disclosure by the FDA's own use of information by limiting it through the second circuit's three-part test. Third, generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution, and that this purpose would be defeated if the court disclosed a manufacturer's extremely valuable information to competitors. Finally, biotech manufacturers can protect their trade secrets by invoking Federal Rules of Civil Procedure 26(c) against discovery requests for documents and Rule 45 against subpoenas. Therefore, trade secret law is a viable and stable alternative to patent protection for biotech and pharmaceutical manufacturers.

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4. *Public Health Service Act*, 42 U.S.C.§§201-300; Richard A. Epstein, The Constitutional Protection of Trade Secrets and Patents Under the Biologics Price Competition and Innovation Act of 2009, 66 Food & Drug L.J. 285, 285 (2011).

5. *Rohm & Haas Co. v. Roberts Chems.*, Inc., 245 F.2d 693, 699 (4th Cir. 1957)

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19. *Id.* § 20.20(b).

20. 21 C.F.R. § 20.61(a).

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24. *Id.* § 552(a)(2)(A).

25. *Id.* § 552(a)(3) (emphasis added).

26. *Id.* § 552(a)(3)(C).

27. *Id.* § 552(a)(3)(B).

28. *Id.* § 552(b)(3) (*id.* § 552(b)(3)(A)(i)-(ii); (B))).

29. *Id.* § 552(b)(3)(A)(i)-(ii).

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50. *Nycomed, 2010 U.S. District LEXIS 20788, at *12.*

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74. *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1368 (Fed. Cir. 2012). Id. at 1362 (Rader, J., dissenting).

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EXHIBIT F

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Hannah-Alise Rogers

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TRADE SECRET RISING: PROTECTING EQUIVALENCY TEST RESEARCH AND DEVELOPMENT INVESTMENTS AFTER *MOMENTA V. AMPHASTAR*

Hannah-Alise Rogers[*]

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[*] Hannah-Alise is a native of Atlanta, Georgia, and attends law school at the University of Georgia School of Law. Her primary interests are healthcare finance and regulatory law, and she hopes to begin her practice in Washington, D.C. after graduation. Hannah-Alise would like to thank Professor Joseph Miller and the staff of the *Journal of Intellectual Property Law* for their help in preparing this Note for publication.

I. INTRODUCTION

The United States has the largest and fastest growing drug market in the world, and the demand for generic drugs is steadily growing.[1] The pharmaceutical industry is responsible for over three million American jobs, and pharmaceutical companies invest millions of dollars in promoting the research and development of new and generic drugs.[2] In order to retain their competitive advantage, most pharmaceutical drug manufacturers seek patent protection.[3] Manufacturers have learned to think creatively, using a variety of patents—including method, design—and research tool patents—in order to fully protect their lucrative inventions. Congress encourages biomedical research and technological innovation through the patent system.[4] Congress heavily regulates the pharmaceutical industry both directly through status such as the Federal Food, Drug, and Cosmetics Act[5] and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act),[6] and indirectly through regulations promulgated by the Food and Drug Administration (FDA).[7] Several volumes of the Code of Federal Regulations are specifically dedicated to describing what manufacturers must do in order to market a drug in the United States.[8]

Due to recent congressional legislation and judicial decisions, however, generic drug manufacturers have lost some previously afforded patent protections,[9] specifically with respect to their bioequivalency test method patents. For example, the safe harbor provision of the Hatch-Waxman Act allows competing drug manufacturers to "borrow" information within the patents of their competitors so long as they agree to use the patents in furtherance of submitting information to the FDA.[10] Competing generic drug manufacturers, for example, can take bioequivalency tests disclosed in the

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[1] *The U.S. Pharmaceutical Industry*, SELECTUSA.GOV, http://selectusa.commerce.gov/industry-snapshots/pharmaceutical-and-biotech-industries-united-states (last visited Oct. 14, 2014).

[2] *Id.*

[3] *Getting Generic Drugs Q & A*, FEDERAL TRADE COMM'N, http://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions (last visited Sept. 30, 2014).

[4] JOSEPH MILLER & LYDIA LOREN, INTELLECTUAL PROPERTY LAW: CASES AND MATERIALS 118 (Ver. 3.1 2013).

[5] Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[6] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[7] 21 C.F.R. § 1 (2013).

[8] *Id.*

[9] *See, e.g.*, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348 (Fed. Cir. 2012); Teva Pharm., USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.).

[10] 35 U.S.C. § 271(e)(1) (2013).

applications of their competitors and use the tests to manufacturer their own generic drugs. A bioequivalency test is a method of testing a generic drug that proves that it is equivalent to a name brand drug that has already received FDA approval. All generic drug applications must demonstrate bioequivalency, thus the tests are extremely valuable. Unfortunately, bioequivalency testing methods can be very costly and time consuming to develop, so generic manufacturers patent the tests in an effort to protect them from use by competitors. The safe harbor provision has thus thwarted the protection scheme on which generic manufacturers depended.

The Federal Circuit recently expanded the scope of the safe harbor provision in 2012 in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*[11] A majority of the Federal Circuit in *Momenta* held that via the safe harbor provision, competing generic pharmaceutical manufacturers could use each other's patented bioequivalency testing methods for pre-clinical research and manufacturing without incurring infringement liability.[12] In 2003, Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA) to the FDA to market Enoxaparin, a generic version of the name brand drug Lovenox, which is used to prevent blood clots.[13] As a result of submitting the ANDA, Aventis, the manufacturer of Lovenox, sued Amphastar; after several years of expensive patent litigation, the FDA granted Amphastar's ANDA, allowing it to manufacture enoxaparin.[14] In the meantime, however, before the FDA granted Amphastar's ANDA for enoxaparin, Momenta "borrowed" Amphastar's bioequivalency test, which was publicly disclosed in Amphastar's ANDA and used the test to beat Amphastar to the market by more than a year.[15] This one year boost resulting from "borrowing" Amphastar's patent for bioequivalency allowed Momenta a monopoly on the generic market, resulting in profits of over $260 million per quarter.[16]

This Note argues that the Federal Circuit's holding in *Momenta* threatens manufacturers with a devastating loss of previously available patent protection for measuring the bioequivalency of generic drugs. The Note concludes that trade secret law is the best alternative to patent protection until Congress decides to narrow the scope of the Hatch-Waxman Act's safe harbor provision. Due to the high cost of submitting a New Drug Application or an ANDA to

[11] *Momenta Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).
[12] *Id.* at 1361.
[13] *Id.* at 1351.
[14] *Id.*
[15] *Id.*
[16] *Id.*

the FDA, generic drug manufacturers want to seek protection for their bioequivalency tests so that consumers can reap the benefits of competition. In other words, giving generic manufacturers the ability to protect their bioequivalency tests would incentivize the production of generic drugs, which would in turn benefit consumers. However, in light of *Momenta*, this protection is no longer available through patent law.[17] Additionally, the Federal Circuit's interpretation of Hatch-Waxman's safe harbor provision has frustrated the generic drug manufacturer's ability to protect its research and development investments. Fortunately, a solution exists for generic drug manufacturers who wish to shield their tests and methods for bioequivalency from the hungry eyes of their competitors. Despite the numerous regulations governing disclosure of information submitted to the FDA, including most notably the Freedom of Information Act (FOIA), generic drug manufacturers, using a heightened degree of care, can protect bioequivalency tests as trade secrets.

Part II of this Note first describes the FDA's method of regulating generic drugs, including the process of submitting an ANDA, to demonstrate why this process is important to the patent protection which *Momenta* has recently frustrated for manufacturers. This section then explains how some of the information submitted to the FDA in furtherance of the ANDA can be protected through trade secret law instead of through patent law.

Part II next reviews the relevant parts of the Hatch-Waxman Act and specifically focuses on the evolution of the safe harbor provision, codified at 35 U.S.C. § 271(e)(1). Moreover, this Part explores prior United States Supreme Court opinions leading up to *Momenta* which have interpreted the safe harbor provision and demonstrates that the scope of the safe harbor provision has been expanded to such an extent that protection via method patents for bioequivalency tests is no longer available.

Additionally, Part II summarizes the current state of trade secret law and demonstrates how a bioequivalency test could qualify as a trade secret. This part also discusses the four potential threats of disclosure that a bioequivalency test trade secret could face, including FOIA requests, FDA use, and litigation; related threats, including the common law right of public access and discovery requests.

Part III argues that trade secret law is not only available to generic manufacturers but is ultimately a better alternative to protecting bioequivalency tests than patent law. Part III demonstrates how generic manufacturers can overcome threats of disclosure of their trade secrets presentation FOIA requests, FDA use and disclosure, and litigation.

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[17] *Id.* at 1362.

II. BACKGROUND

A. FDA SUBMISSION REQUIREMENTS FOR GENERIC DRUGS

Under the Food, Drug and Cosmetics Act of 1938, Congress delegated to the FDA the power to enact specific regulations concerning requirements for marketing new and generic drugs.[18] A new drug or generic bioequivalent may not be placed on the market without prior FDA approval.[19] The process for gaining FDA approval is quite extensive, so this Note only discusses the most relevant and important requirements relating to generic drugs.

First, in order to gain FDA approval to manufacture a generic drug, the manufacturer must submit an ANDA. The application must be within one of the FDA's delineated categories of acceptable drug products.[20] ANDAs may be submitted for "[d]rug products that are bioequivalent, or the same as a listed [i.e. name brand] drug. For determining the suitability of an [ANDA], the term 'same as' means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use."[21] Within sixty days of receiving an ANDA, the FDA will conduct a preliminary review of the application to determine whether it may be filed.[22] If the filing of an application is permitted, the party can submit it, and the FDA will then either send an approval of the application or deny it within 180 days of submission.[23]

A central requirement for a successful ANDA is that the generic drug must be the bioequivalent of the listed (i.e., name brand) drug.[24] A bioequivalency test is defined as "[i]nformation that shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies."[25] In other words, rather than submitting a New Drug Application, a manufacturer who wants to produce a generic version of an already existing drug proves in its ANDA that the generic is the same as the name brand drug; as a result, generic drug manufacturers are not required to demonstrate safety or efficacy of the drug in their ANDA, since these were already demonstrated in the application of the original manufacturer.[26] Bioequivalency tests are thus of critical

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[18] P.L. 75-717, 52 Stat. 1040 (1938).
[19] 21 C.F.R. § 314.105(a) (2013).
[20] *Id.* § 314.92(a).
[21] *Id.* § 314.92(a)(1). For more on the requirements for the acceptable types of drug products, see *id.* §§ 314.92(a)(1), 314.122.
[22] *Id.* § 314.101(a)(1).
[23] *Id.* § 314.100(a).
[24] *Id.* § 314.94(a)(7).
[25] *Id.* § 314.94(7)(i).
[26] *See supra* note 1.

importance to ANDAs, and even the analytical and statistical methods used in determining bioequivalency are subjected to FDA regulation.[27]

In addition, a completed ANDA form must contain the following parts: a table of contents; a basis for submission (meaning the application must refer to a listed drug); the conditions under which the drug can be used; the drug's active ingredients (which must be the same as the active ingredients in the listed drug); the route of administration, strength, and dosage form of the drug (which must be the same as those in the listed drug); bio-equivalence (discussed further below); the labeling and proposed labeling for the drug; the chemistry, manufacturing process, and controls of the drug; any drug samples requested by the FDA; any patent certifications used in the manufacture of the drug; and a statement of financial certification or disclosure.[28] Additionally, "[a] complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval."[29] As discussed in Part III, the FDA may freely use the information that it receives in an ANDA, and the FDA, like other Federal Agencies, has a broad disclosure policy, meaning that the FDA allows the public to obtain Agency information whenever appropriate.[30]

Once a method for determining bioequivalency is established, generic drugs can be quickly and more easily produced because the drug manufacturers can demonstrate that the generic is the same as the listed drug, which has already extensively tested by the FDA. Generic competitors thus have a great incentive to steal these bioequivalency testing methods in order to accelerate the process of submitting an ANDA. Because the process of developing a bioequivalency test can be expensive and time consuming, generic drug manufacturers need assurance that the tests will receive some type of protection in order to incentivize their development.[31] Given the breadth of information, time, and money required to submit an ANDA, generic manufacturers seek patent protection in order to make their investments worthwhile.

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[27] 21 C.F.R. § 314.94(7)(iii); *see also id.* §§ 56.104, 56.105 (providing exceptions to normal IRB requirements).

[28] *Id.* §§ 314.94(a)(1)–(12).

[29] *Id.* § 314.94(7)(i).

[30] *See infra* text accompanying note 162 and discussion that follows.

[31] *See, e.g.*, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348 (Fed. Cir. 2012) (plaintiff patent holder sought enforcement of its method patent for a bioequivalency test); Teva Pharm. USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.) (involving a similar fact pattern).

B. THE SCOPE OF THE SAFE HARBOR PROVISION OF THE HATCH-WAXMAN ACT

In order to demonstrate the breath of the problem that the Federal Circuit's ruling in *Momenta v. Amphastar* has caused, this section discusses how the FDA's regulations regarding generic drugs intersect with the Hatch-Waxman Act. The relationship between the Hatch-Waxman Act and RDA regulations is critical for understanding why the Federal Circuit's holding in *Momenta* frustrated the usefulness of patent protection for bioequivalency research and development. In order to fully understand the goals and problems of the Hatch-Waxman Act, it is first helpful to review the history which led to the statute's enactment.

Before the Hatch-Waxman Act became effective in September of 1984, there were no statutory provisions to protect pharmaceutical companies from a competitor's allegations of patent infringement when they used another's patented technology to perform pre-approval clinical research.[32] Congress enacted the Act's safe harbor provision "to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement."[33] The Act specifically overruled the Federal Circuit's opinion in *Roche Prods. v. Bolar Pharmaceutical Co.*[34] *Roche* held that a competing drug manufacturer infringes by using a competitor's patent for pre-clinical research because borrowing patented information for research purposes falls outside of the scope of the experimental use rule,[35] which "ends with an actual reduction to practice."[36] The Federal Circuit declared, "[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of scientific inquiry, when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[37] This precedent left no protection to pharmaceutical companies alleged to infringe by competitors when they used another's patented technology to perform FDA pre-approved clinical research.

The safe harbor provision of the Hatch-Waxman Act,[38] now clarifies:

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[32] Roche Prods. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).

[33] H.R. REP. NO. 98-857, pt. 1, at 45 (1984) (quoting Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1362 (Rader, C.J., dissenting)).

[34] *Id.* pt. 2, at 27.

[35] *Roche Prods.*, 733 F.2d at 863. The experimental use rule is "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement [and] is not an infringement of the rights of the patentee." *Id.* at 862 (internal quotations omitted) (internal citations omitted).

[36] Nordberg Inc. v. Telsmith, Inc., 881 F. Supp. 1252, 1285 (E.D. Wis. 1995) (internal quotation marks omitted).

[37] *Roche Prods.*, 733 F.2d at 863.

[38] H.R. REP. NO. 98-857, pt. 2, at 27 (1984).

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[39]

Since the passage of the statute, the Supreme Court has interpreted its meaning fairly expansively.[40] This Note will next briefly summarize the Supreme Court's interpretations of the safe harbor provision, leading to the Federal Circuit's most recent expansion in *Momenta*.

The controversy over the scope of the safe harbor provision began early in the statute's history; the Supreme Court first interpreted the safe harbor provision only six years after it was enacted in *Eli Lilly & Co. v. Medtronic, Inc.*[41] *Eli Lilly* concerned whether the safe harbor provision applied to patented medical devices in addition to prescription drugs.[42] The Supreme Court broadened the application of the statute to not only to drug patents, but also to medical devices.[43] In writing for the majority, Justice Scalia reached this expansive holding by citing the Act's purpose according to the legislative history "to respond to two unintended distortions on the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval."[44] According to the majority, Congress designed the safe harbor provision to prevent the patentee from having an extended monopoly on the market simply by virtue of the amount of time it takes another company to produce a bioequivalent drug.[45] The majority additionally argued that the statute "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval."[46]

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[39] 35 U.S.C. § 271(e)(1) (2012).

[40] *See* 496 U.S. at 665 (finding no infringement under § 271(e)(1) in the case of a patented medical device); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (holding that the use of a patented compound was protected by § 271(e)(1) as long as it was reasonable to believe that the compound tested could be submitted to the FDA at some later time and the experiments for which the compound was used would produce information relevant to an application).

[41] 496 U.S. 661.

[42] *Id.* at 663.

[43] *Id.* at 665.

[44] *Id.* at 669.

[45] *Id.* at 672–73.

[46] *Id.* at 671.

However, Justices Kennedy and White dissented, arguing the safe harbor provision should not apply to anything beyond obtaining market approval for a drug, and that the statute should not apply to "all" products regulated by the FDA.[47] Justice Kennedy explained that the testing of medical devices should not be protected by the safe harbor because Congress could not have intended for such an extraordinary meaning of the specific language in the statute.[48]

In 2005, the Supreme Court again interpreted the scope of the safe harbor provision in *Merck KGaA v. Integra Life Sciences I, Ltd.*[49] *Merck* posed the question of whether a manufacturer could use patented inventions during preclinical research under the immunity of the safe harbor provision when the results were not actually submitted to the FDA.[50] Justice Scalia delivered a short, and probably too informal, unanimous opinion, holding that the safe harbor provision's exception to infringement:

> [N]ecessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.[51]

Thus, the *Merck* Court again widened the scope of the safe harbor provision.

Following suit, the Federal Circuit further expanded the safe harbor provision of the Hatch-Waxman Act in *Momenta v. Amphastar.* The issue in *Momenta* was whether the defendant generic manufacturer lawfully used the plaintiff competitor's patented test for bioequivalency to test its own form of the generic drug Enoxaparin.[52] Defendant Amphastar argued that it did not infringe because it used the plaintiff's patent to test their own version of the generic drug Enoxaparin and submitted these test results to the FDA, therefore falling within the scope of the safe harbor.[53] The court agreed with the defendant that its use of momenta's bioequivalency test for Enoxaparin was "solely for uses reasonably related to the development and submission of information under a Federal law"; and thus was permissible under the safe

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[47] *Id.* at 680 (Kennedy, J., dissenting).
[48] *Id.*
[49] 545 U.S. 193 (2005).
[50] *Id.* at 195.
[51] *Id.* at 202.
[52] Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1350 (Fed. Cir. 2012).
[53] *Id.* at 1352–53.

harbor provision.[54] The majority relied primarily on the text of the statute to support its position, arguing specifically that the phrase 'under a federal law' "extend[ed] beyond just the 'most barebones information' required by the FDA, and instead encompass[ed] all 'materials the FDA demands in the regulatory process.' "[55] Chief Judge Rader, however, relied on congressional purpose to dictate a different result.[56]

In a strong dissent, Chief Judge Rader argued that Amphastar's actions exceeded the scope of the safe harbor provision because Amphastar used Momenta's patent for more than the mere submission of information to the FDA.[57] In his view, "Amphastar stepped in and took Momenta's patented invention without permission and used it to manufacture each commercial batch [of Enoxaparin] it sells on the market."[58] Additionally, the fact that Amphastar could only compete with Momenta by using its patent strengthened Chief Judge Rader's conclusion that the safe harbor provision should be more limited in scope.[59] In reaching this conclusion, Chief Judge Rader relied on legislative history to support his argument that Congress did not intend to give manufacturers the right to use another's patented process to place a competing drug on the market,[60] and criticized the majority for totally ignoring it.[61] The safe harbor provision, he noted, was a congressional compromise because of its limited scope in time, quantity, and type.[62] The time period covered by the safe harbor was only for pre-market approval; in other words, after the FDA approves the drug, the safe harbor provision does not protect further marketing activities.[63] In terms of the safe harbor provision's limitations on quantity and type, Chief Judge Rader explained that the statute "only applies to experimentation—and therefore would have limited impact on the patentee's exclusivity during the life of the patent."[64] In all, Chief Judge Rader concluded that the safe harbor provision did not protect Amphastar from its use of

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[54] *Id.* at 1353 (quoting 35 U.S.C. § 271(e)(1)).

[55] *Id.* at 1356 (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1683 (2012)).

[56] *Id.* at 1362 (Rader, J., dissenting).

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] *Id.* at 1362–63 (quoting H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984)).

[61] *Id.* at 1366.

[62] *Id.* at 1365 (citing *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcom. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 696 (1984) (letter from Pharmaceutical Manufacturers Association)).

[63] *Id.*

[64] *Id.* at 1365–66 (citing H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984)).

Momenta's patented bioequivalency test because Amphastar continued to use the test after it gained FDA approval, thus destroying Momenta's right to exclude.[65] As he lamented, "This result will render worthless manufacturing test method patents."[66]

Chief Judge Rader reached this fear that test method patents would no longer offer protection to patent holders by considering the implications of the majority's holding.[67] He argued that the majority of the Supreme Court and the Federal Circuit have interpreted the safe harbor provision so broadly as to allow competitors to use patented testing methods not just for pre-clinical research but also for manufacturing.[68] Patents exist to define the exclusion rights of their holders,[69] but the exclusion rights in this scenario have been all but snatched away, presenting a problem for generic drug manufacturers who spend millions of dollars developing tests to determine bioequivalency, and then seek to protect these tests from the hungry eyes of their competitors.

C. A BRIEF OVERVIEW OF PATENT PROTECTION

In order to understand what generic manufacturers have lost by their inability to protect their bioequivalency tests via patent law, this section briefly reviews the protection that manufacturers would receive from patents absent the *Momenta v. Amphastar* holding. Patent law's origin rests in the United States Constitution,[70] which has been codified to protect "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" that is invented or discovered.[71] In order to receive patent protection for an invention falling within one of these eligible categories, one must disclose his or her invention to the Patent Trademark Office (PTO)[72] and meet the other statutory requirements of novelty and non-obviousness.[73] Patent law's scheme of protection of information via this disclosure process could be seen as the opposite of trade secret protection, which attempts to retain the value of information by protecting it against public disclosure.[74]

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[65] *Id.* at 1367.
[66] *Id.* at 1362.
[67] *Id.*
[68] *Id.* at 1361. *See also* Merck KGaA v. Integra Life Sciences I, Ltd., 545 U.S. 1953 (2005).
[69] *Id.*
[70] U.S. CONST. art. 1, § 8, cl. 8.
[71] 35 U.S.C. § 101 (2006).
[72] MILLER & LOREN, *supra* note 4, at 117.
[73] 35 U.S.C. §§ 102–103.
[74] MILLER & LOREN, *supra* note 4, at 27.

Assuming that all the requirements for a valid patent are met,[75] the patentee receives protection for his or her invention for a period of twenty years.[76] During this time, the patentee holds an exclusive right to use the patented process, machine, manufacture, or composition of matter.[77] In the context of bioequivalency testing methods of pharmaceutical drugs testing, the applicable patent eligible category is "process." Therefore, this Note proceeds referring solely to "process" patents, also known as method patents.

If a patentee discovers that another entity is performing its patented process, the patentee can sue this competitor for infringement.[78] If a court finds that the competitor infringes, the patentee is entitled to monetary damages and/or an injunction.[79] Overall, patent protection is bent towards protection for an invention via disclosure of that invention,[80] unlike trade secret protection, discussed below, which affords protection for inventions by keeping them a secret.[81]

D. A LOOK AT THE STATE OF TRADE SECRET LAW AND THE POTENTIAL THREATS OF DISCLOSURE

A generic manufacturer need not register its bioequivalency test as a trade secret, but in order to qualify for trade secret protection, a bioequivalency test must meet the legal definition of a "trade secret."[82] This part examines several common definitions of "trade secret," which will be used in Part III to demonstrate how a bioequivalency test fits within the scope of protectability. This section also briefly introduces the ways in which a bioequivalency test protected by trade secret law can be disclosed, including through a FOIA request, FDA use, discovery requests, and the common law right of public access.

Although trade secret law originally evolved under state common law, the Uniform Trade Secrets Act (UTSA),[83] was created to make state trade secret law more homogenous and has been adopted by all but three states.[84] The

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[75] For more information on the requirements for a valid patent, see *id.* at 129–54. *See also* 35 U.S.C. §§ 101–103, 112.
[76] 35 U.S.C. § 187.
[77] *Id.* § 254.
[78] *See id.* § 255.
[79] *Id.* §§ 277–278.
[80] *Id.* § 118.
[81] *Id.* § 27.
[82] MILLER & LOREN, *supra* note 4, at 27.
[83] Unif. Trade Secrets Act (1979) (amended 1985).
[84] MILLER & LOREN, *supra* note 4, at 28.

following discussion refers to the UTSA as adopted by New Jersey, a state home to a large percentage of the United States' drug manufacturers.[85]

The New Jersey UTSA outlines the definition of a 'trade secret' and the circumstances under which a trade secret can be misappropriated:

> "[T]rade secret" means information, held by one or more people, without regard to form, including a formula . . . method . . . technique . . . or process that: (1) derives independent economic value . . . from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[86]

The UTSA thus provides direction to generic drug manufacturers seeking to protect their bioequivalency testing methods via trade secret law. However, each manufacturer should look at the specific adoption of the UTSA in their state in order to fully understand the scope of the trade secret protection offered.[87]

In addition to the UTSA, the FDA also promulgates rules and regulations regarding trade secrets, so is important for generic manufacturers to keep the FDA's definition of "trade secret" in mind when submitting their ANDAs.[88] Because the FDA receives a great deal of information from generic drug manufacturers, disclosure of this information to the public is of high importance to a manufacturer seeking protection. The FDA's provisions regarding the protection of submitted information strikingly states that "[t]he [FDA] will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information."[89] It continues: "Except where specifically exempt pursuant to the

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[85] *Pharmaceuticals*, STATE OF NEW JERSEY BUSINESS PORTAL, http://www.nj.gov/njbusiness/industry/pharmaceutical/ (last visited Sept. 30, 2014).

[86] N.J. STAT. ANN. § 56:15-2 (West 2012).

[87] With the exception of Massachusetts and New York, each state has adopted some form of the UTSA. While the laws are similar, it is helpful to refer to a state's specific version of the UTSA as a measure of precaution. For a full list of each state's UTSA law, see *Trade Secrets Laws: State Law*, ORRICK, HERRINGTON & SUITCLIFF, LLP, http://blogs.orrick.com/trade-secrets-watch/trad e-secrets-laws/ (last visited Nov. 13, 2014).

[88] *See* 21 C.F.R. § 20.61 (2013).

[89] *Id.* § 20.20(a).

provisions of this part, all FDA records shall be made available for public disclosure."[90]

Due to the FDA's proclivity towards disclosure of information, the FDA's definition of "trade secret" is essential for the protection of information.[91] Courts have grappled with how expansively to construe the definition,[92] which reads:

> A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.[93]

Because requests for information made under the FOIA are a common way in which information known by the FDA can be disclosed, generic manufacturers will likely want to know whether trade secrets that are submitted to the FDA as a part of an ANDA could be disclosed by a FOIA request.[94] The Freedom of Information Act first became effective in 1967, and controls the public disclosure of previously unreleased information from federal agencies.[95] The primary purpose of the FOIA is to enable the public to access government records in order to gain a greater understanding of the government.[96] FOIA disclosures include everything from substantive and procedural rules regarding disclosure of information,[97] administrative case law reporting,[98] and statements of policy and agency interpretations.[99] Perhaps the most controversial part of FOIA is found in section 3:

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[90] *Id.* § 20.20(b).

[91] *Id.* § 20.61(a) ("The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.").

[92] *See, e.g.*, Public Citizen Health Research Group v. Food & Drug Admin., 704 F.2d 1280 (D.C. Cir. 1983).

[93] 21 C.F.R. § 20.61(a).

[94] Pub. L. No. 89-487, 80 Stat. 250 (1967) (codified at 5 U.S.C. § 552).

[95] *What is FOIA*, FOIA.GOV, http://www.foia.gov/about.html (last visited Nov. 14, 2014).

[96] *Id.*

[97] 5 U.S.C. § 552(a)(1)(A)–(E) (2012).

[98] *Id.* § 552(a)(2)(A).

[99] *Id.* § 552(a)(2)(B).

> Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon *any* request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, *shall* make the records promptly available to any person.[100]

The agency must also perform a reasonable search to find the information[101] and must provide the information in the format requested.[102] Like many other federal agencies, the FDA has its own Freedom of Information Act Office, called the Food and Drug Administration Division of Freedom of Information,[103] wherein a person who is seeking information from the FDA must submit a request.[104]

Although the FOIA attempts to make as much agency information available to the public as possible, there are some exceptions to what information a petitioner can receive. For example, agencies may withhold information that is labeled confidential for the purposes of national security by an executive order,[105] information that is solely related to agency personnel rules,[106] and information that is "exempted from disclosure by statute."[107] For information to be exempt by a specific statute, the statute must be clear as to what type of information may be withheld[108] and must cite to the FOIA, in limited circumstances.[109] Finally, exceptions to FOIA also exist for "trade secrets and commercial or financial information obtained from a person and privileged or confidential,"[110] agency memorandums,[111] and medical/personnel files.[112] Although an exemption exists

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100 *Id.* § 552(a)(3) (emphasis added).
101 *Id.* § 552(a)(3)(C).
102 *Id.* § 552(a)(3)(B).
103 21 C.F.R. § 20.30(a) (2013).
104 *Id.* § 20.30(b).
105 5 U.S.C. § 552(b)(1)(A) (2012).
106 *Id.* § 552(b)(2).
107 *Id.* § 552(b)(3) (to be exempted, the statute in question must "(i) require[] that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or (ii) establish[] particular criteria for withholding or refer[] to particular types of matters to be withheld; and (B) . . . specifically cite [] to this paragraph." (*id.* § 552(b)(3)(A)(i)–(ii); (B))).
108 *Id.* § 552(b)(3)(A)(i)–(ii).
109 *Id.* § 552(b)(3)(B).
110 *Id.* § 552(b)(4).
111 *Id.* § 552(b)(5).
112 *Id.* § 552(b)(6).

for trade secrets, manufacturers will have concerns that their bioequivalency tests, which are worth millions of dollars, may not fit within the scope of protection.

Hypothetically, if a generic manufacturer were to choose to protect its bioequivalency test via trade secret law, a competitor could try to access the test information by submitting a FOIA request for it. Anyone who wishes to request information from the FDA must submit a FOIA request in writing to the FDA's headquarters in Maryland.[113] The writing must reasonably set forth the information being requested.[114] So long as the writing reasonably details the information sought, "[e]very reasonable effort shall be made by the [FDA] to assist in the identification and location of the records sought."[115] The person submitting the request must also pay a fee, the amount of which is determined by the type of information requested.[116] If the confidentiality of requested information is uncertain, the FDA will contact the entity who submitted the information and/or who will "be affected by its disclosure before determining" whether to disclose the information.[117]

If the FDA rejects a request for information, "the decision constitutes final agency action that is subject to judicial review."[118] The person requesting the information will be notified of the FDA's rejection and will then have five days after receipt of notification to file a suit in a United States District Court.[119] When trade secret information is requested and disclosure is denied,[120] the FDA will inform the person who submitted the record that he or she must come and defend the record's confidentiality in court.[121] The statute reads, "If the affected person fails to intervene to defend the exempt status of the records . . . the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public disclosure."[122] Thus, the FDA expects the person who submits information classified as a trade secret to defend this status if it is challenged. While defending the trade secret status is not mandatory under the statute, it factors into the FDA's decision of whether or not to disclose the information.[123]

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113 21 C.F.R. § 20.40(a) (2013).
114 *Id.* § 20.40(b).
115 *Id.* § 20.40(b)(2).
116 *See id.* § 20.45(a)(1)–(3).
117 *Id.* § 20.47.
118 *Id.* § 20.48.
119 *Id.*
120 Disclosures are denied under 21 C.F.R. § 20.61.
121 21 C.F.R. § 20.55.
122 *Id.*
123 *Id.*

Finally, even if a generic manufacturer meets the FDA's definition of trade secret when submitting an ANDA and the FDA's disclosure of the information via a FOIA request is limited, both the common law right of public access[124] and discovery requests[125] pose additional threats for generic manufacturers who wish to protect their trade secrets. The common law right of public access can arise during or after a lawsuit and poses a threat to generic manufacturers' ability to protect bioequivalency tests, as courts strive to maintain open records of judicial proceedings. The Second Circuit explains in *Nycomed US, Inc. v. Glenmark Generics, Inc.*, that the right of public access allows open access to judicial documents to provide information to the public in hopes of making the courts appear more legitimate.[126] For the purposes of this Note, the definition of "judicial documents" is particularly relevant because as the Second Circuit declared in *Lugosh v. Pyramid Co. of Onondaga*, judicial documents are presumed to be open to public access, as described in Part III.[127]

In *Stern v. Cosby*, the Second Circuit additionally developed a three-part test to determine whether a judicial document is subject to the common law right of public disclosure.[128] "First, the court must determine whether the documents are indeed judicial documents . . . Second, if the documents are judicial documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it."[129] Altogether the right of public access threatens disclosure of trade secrets. However, a generic manufacturer can successfully argue that bioequivalency tests disclosed in ANDAs should not be subject to the common law right of public access.[130]

Likewise, discovery requests also pose a threat to generic manufacturers who could protect their bioequivalency tests as trade secrets. The Federal Rules of Civil Procedure do not contain an absolute privilege for trade secrets that are requested during discovery,[131] but Rules 26 and 45 can help generic

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[124] *See, e.g.*, Stern v. Cosby, 529 F. Supp. 2d 417 (S.D.N.Y. 2007).

[125] *See, e.g.*, Massey Coal Services, Inc. v. Victaulic Co. of Am., 249 F.R.D. 477 (S.D. W. Va. 2008).

[126] Nycomed US, Inc. v. Glenmark Generics, Inc., No. 08-CV-5023 (CBA), 2010.

[127] 435 F.3d 110, 122 (2d Cir. 2006) (quoting FTC v. Standard Fin. Mgmt. Corp., 830 F.2d 404, 409 (1st Cir. 1987)) ("[R]elevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings become documents to which the presumption of public access applies.").

[128] Stern v. Cosby, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007).

[129] *Id.* (quoted in Nycomed US, Inc. v. Glenmark Generics, Inc., 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.) (internal quotation marks omitted)).

[130] *See infra* notes 196–208.

[131] *See generally* Paulsen v. Case Corp., 168 F.R.D. 285 (C.D. Cal. 1996).

manufacturers to protect their bioequivalency test trade secrets from disclosure during litigation. Rule 26 provides a scenario in which a party may receive a protective order from the court in order to guard against the disclosure of a trade secret[132]: "The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action."[133] Then, the rule states, "the court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" by several following methods.[134] One of the following ways to protect a party includes: "requiring that a trade secret or other confidential research development, or commercial information not be revealed or be revealed only in a specific way."[135] Because any relevant evidence will lend a presumption of admissibility, the party seeking protection has the burden of proof that the information should not be disclosed.[136] Thus, although there is no per se protection of trade secrets in the Federal Rules of Civil Procedure,[137] generic manufacturers could use Rule 26 and case law relating to discovery and the common law right of public access to argue that their bioequivalency tests protected as trade secrets should not be disclosed.

Like Rule 26, Rule 45 also helps ensure that trade secrets are not wrongfully disclosed during discovery by protecting trade secrets from subpoenas. A subpoena is an order from a government agency, usually a court, which compels a witness to testify or produce evidence.[138] In relevant part, Rule 45 states, "To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information. . . ."[139] Subsequent case law has stated that when a court is deciding whether to quash a subpoena which seeks information marked as a trade secret, "a court must evaluate all the circumstances and balance, *inter alia*, the requesting party's need for the information and the potential prejudice imposed on the requested party."[140] Furthermore, the factors to be balanced include "the relevance of the discovery

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[132] FED. R. CIV. P. 26(c)(1).
[133] *Id.*
[134] *Id.*
[135] *Id.* at 26(c)(1)(G).
[136] *In re* Fosamax Prods. Liab. Litig., 2009 U.S. Dist. LEXIS 70246, at *31 (S.D.N.Y.).
[137] *See* Paulsen v. Case Corp., 168 F.R.D. 285, 289 (C.D. Cal. 1996).
[138] Merriam Webster, *Subpoena*, MERRIAM WEBSTER ONLINE, http://www.merriam-webster.com/dictionary/subpoena (last visited Sept. 30, 2014).
[139] FED. R. CIV. P. 45(d)(3)(B)(i).
[140] Insulate America v. Masco Corp., 227 F.R.D. 427, 432 (W.D.N.C. 2005) (citations omitted).

sought, the requesting party's need, and the potential hardship to the party subject to the subpoena."[141]

Altogether, the numerous rules that govern the FDA's submission of information, FOIA requests, the FDA's use, the common law right of public access, and discovery requests could each pose a threat to manufacturers who wish to protect their bioequivalency tests via trade secret law. Nevertheless, there are various situations in which a competing drug manufacturer could attempt to access a bioequivalency test protected by trade secret law, as next explained in Part III. These situations include disclosure requests from third parties,[142] threats of disclosure or use by the FDA,[143] and the threat of disclosure during litigation through the assertion of common law right of public access or a discovery request.[144] A generic manufacturer seeking to protect its bioequivalency test via trade secret law should pay close attention to the way courts define the scope of trade secret and the various methods that competitors can use to seek disclosure of trade secret information.

III. ANALYSIS

Given *Momenta*'s holding that the safe harbor provision of the Hatch-Waxman Act encompasses a drug manufacturer's use of another's bioequivalency testing methods for pre-clinical research and manufacturing, patent law offers little to no protection for generic manufacturers who wish to protect their bioequivalency tests from appropriation by competitors.[145] Because FDA regulations of ANDAs are complex and require each manufacturer to make a specific showing of how it meets the requirements to legally manufacture a drug, as discussed above, the FDA requires generic drug manufacturers to disclose their bioequivalency testing methods to ensure that a drug in production is both safe and effective.[146] Due to the extensive information required by the FDA, ANDAs are therefore expensive to produce. Moreover, since bioequivalency tests can be difficult, time consuming, and expensive to develop, generic manufacturers often use patent protection to

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[141] Dorel Juvenile Grps., Inc. v. Summer Infant, Inc., C 06-91 S, 2006 U.S. Dist. LEXIS 77906 (D.R.I. Oct. 11, 2006) (quoting Heat & Control, Inc. v. Hester Indus., Inc., 785 F.2d 1017, 1024 (Fed. Cir. 1986)).

[142] *See* Public Citizen Health Research Group v. Food & Drug Admin., 704 F.2d 1280 (D.C. Cir. 1983).

[143] *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984) (involving a similar situation in the Environmental Protection Agency).

[144] *See* Nycomed US, Inc. v. Glenmark Generics, Inc., 2010 U.S. Dist. LEXIS 20788 (S.D.N.Y.).

[145] Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348 (Rader, J., dissenting).

[146] *See supra* notes 17–25 and accompanying text.

make investment in bioequivalency testing methods worthwhile. However, after the *Momenta* holding, adequate patent protection of bioequivalency tests has been lost, leaving generic manufacturers little incentive to invest in their development. Nevertheless, trade secret law endures to protect generic drug manufacturers' bioequivalency tests from appropriation by competitors. This Note argues that trade secret is in fact the best and most natural method for protecting bioequivalency tests after *Momenta*, and therefore seeks to advise generic drug manufacturers of the potential hurdles to overcome in gaining such protection.

This section first discusses the scope of the definition of trade secret in various contexts, keeping in mind that competitors who seek the information will try to attack the definitions of both the UTSA and the FDA. Next, this section explores the different ways for generic manufacturers to overcome potential threats of misappropriation, in particular by jumping three different anticipated hurdles to trade secret protection. These hurdles are: a FOIA request made by a third party, potential use and disclosure of protected information via FDA regulations, and disclosure during litigation via the common law right of public access and the discovery process. Finally, this section argues how each of these potential threats to protecting bioequivalency tests can be avoided.

A. THE SCOPE OF THE DEFINITION OF "TRADE SECRET"

Before seeking trade secret protection for a bioequivalency testing method, it is important to look at the exact definition of "trade secret" in order to understand exactly what can be protected. As was explored above, there are different working definitions of what constitutes a trade secret, and each is important different contexts.[147] Generic manufacturers seeking to protect their bioequivalency tests via trade secret law should this to make sure to distinguish these definitions from each other and understand when each definition applies. Two of the relevant definitions of trade secret are the UTSA definition[148] and the FDA's definition.[149]

A bioequivalency testing method would be considered a 'trade secret' for the purposes of both the UTSA and the FDA's definitions. The UTSA has a broad definition of "trade secret," including formulas, methods, techniques, or processes.[150] Similarly the FDA, defines a trade secret as, "[A]ny commercial

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147 *See supra* notes 77–87 and accompanying text.
148 *See supra* note 92.
149 21 C.F.R. § 20.61 (2013). *See also supra* note 93.
150 *See supra* note 92.

valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."[151] A bioequivalency test would easily classify as a trade secret under either of these definitions as a formula is used for the purposes of demonstrating that a generic drug is the bioequivalent of, or the same as, the name brand.[152] Since bioequivalency testing methods should meet either the UTSA or FDA definition of trade secret, generic manufacturers do retain an incentive for economic investment in their development, despite the inadequacy of patent protection to do the same after the *Momenta* court's holding.

B. THE THREAT OF DISCLOSURE

Once a generic manufacturer decides to protect bioequivalency test as a trade secret, there are three potential ways in which a generic drug manufacturer's trade secret could be disclosed: first, through a FOIA request; second, through use by the FDA itself; and third, through an assertion of the common law right of public access during the discovery process of litigation.

1. Overcoming the Threat of Disclosure Via a FOIA Request. The D.C. Circuit's discussion of the scope of trade secret protection in the FOIA context in *Public Citizen Health Research Group v. Food & Drug Administration* demonstrates that this scope is broad enough to protect bioequivalency tests.[153] In *Public Citizen Health*, the plaintiff consumer advocacy group sought information from the FDA regarding the safety and effectiveness of an intraocular lens that had been on the market for several years.[154] The manufacturer of the intraocular lenses submitted clinical test results to the FDA, and the manufacturer objected to the disclosure of these results to the petitioner, who had made a FOIA request for them.[155] The court was asked to determine whether the requested records were "immune from disclosure under Exemptions 3 and 4 of the FOIA."[156] As the court explained, "[t]hese exemptions allow the court to withhold, respectively, (1) records that are 'specifically exempted from disclosure by statute' if the relevant statute satisfies one of two limiting conditions and (2) 'trade secrets and

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[151] 21 C.F.R. § 20.61.

[152] *See* Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1350 (Fed. Cir. 2012) (discussing the "sufficient information [needed] to establish that the generic drug has the same active ingredients as the reference drug").

[153] Public Citizen Health Research Grp. v. Food & Drug Admin., 704 F.2d 1280 (D.C. Cir. 1983).

[154] *Id.* at 1283.

[155] *Id.*

[156] *Id.* at 1282.

commercial or financial information obtained from a person and privileged or confidential."[157] In affirming in part and reversing in part, the D.C. Circuit held that the district court "erred in its application of Exemption 3 and adopted an overly broad construction of the term 'trade secrets' in Exemption 4"; therefore, the court partially granted the petitioner's request for the drug manufacturer's clinical test results.[158]

The court's discussion of Exemption 4, and more specifically whether "the requested documents constitute 'trade secrets' [and are therefore] exempt from disclosure"[159] illustrates that manufacturers can shield bioequivalency tests from third parties urging disclosure through a FOIA request by protecting them as trade secrets. After evaluating several different definitions of "trade secrets" at common law, and finding that the Restatement of Torts's expansive definition[160] "would classify virtually all undisclosed health and safety testing data as trade secrets,"[161] the court settled on a more restrictive definition to adopt in FOIA cases.[162] "Defined in its narrower common law sense," a trade secret is "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation of substantial effort."[163] In arguing that this is the best definition of trade secret, the court stated that it "incorporates a direct relationship between the information at issue and the productive process."[164]

Although the court in *Public Citizen Health* chose the more restrictive definition of trade secret, believing that it "hews more closely to language and legislative intent of FOIA than does the *Restatement* approach,"[165] this definition can still be used to protect bioequivalency testing methods. A bioequivalency testing method should qualify as a trade secret because it is "a commercially

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157 *Id.*; *see also* 5 U.S.C. § 522(b)(3), (4).

158 *Public Citizen Health*, 704 F.2d at 1282.

159 *Id.* at 1286; *see also* 5 U.S.C. § 522(b)(4).

160 RESTATEMENT OF TORTS § 757 cmt. b (1939) ("A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."). The definition of 'trade secret' as specified in the Restatement has been adopted by other courts. *See, e.g.*, Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).

161 *Public Citizen Health*, 704 F.2d at 1286 (quoting Thomas McGarity & Sidney Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 861 (1980)).

162 *Id.* at 1286–87.

163 *Id.* at 1288.

164 *Id.*

165 *Id.* at 1289.

valuable . . . formula . . . that is used for the making of trade commodities" i.e., a prescription drug, that is the "product of either innovation or substantial effort."[166] There is no doubt that a bioequivalency test would be considered "commercially valuable"; the competing generic manufacturer in *Momenta*, for example, was able to make over $260 million per quarter after using the patent holder's bioequivalency test.[167] Furthermore, a bioequivalency test certainly qualifies as a formula, as it is used for the making of pharmaceutical drugs, which also constitute "trade commodities." There is also a direct relationship between the bioequivalency testing methods and the productive process of manufacturing drugs, unlike the information requested in *Public Citizen Health*.[168] Thus, even under the more restrictive definition of 'trade secret' as used by the D.C. Circuit and some other courts in determining the possibility of disclosure via a FOIA request, a generic manufacturer should be able to protect bioequivalency tests as trade secrets and will be immune from disclosure under Exemption 4 of FOIA.[169]

2. Overcoming Threats of Disclosure Via the FDA's Use and Disclosure of Trade Secrets. In addition to FOIA requests, competitors could potentially gain access to bioequivalency tests protected by trade secret law through the FDA's own use and disclosure of the protected information. While it is true that bioequivalency test trade secrets would have to be disclosed to the FDA in order to submit an ANDA, generic manufacturers should be assured that the FDA can only disclose protected information to third parties under limited circumstances.[170]

The Supreme Court addressed the question of when an agency may use and disclose information that is freely submitted by a manufacturer seeking agency approval to produce a product in *Ruckelshaus v. Monsanto*,[171] whose reasoning can be applied to bioequivalency tests to demonstrate that the scope of trade secret protection is broad enough to prevent the FDA from disclosing the information. The issue in the case was whether a pesticide manufacturer who submitted an application for market approval of its pesticide to the Environmental Protection Agency (EPA) could claim trade secret protection

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166 *Id.*

167 Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1351 (Fed. Cir. 2012).

168 *See* 704 F.2d at 1290 ("[W]e conclude that [the records at issue] are not protected under the first prong of Exception 4. The relationship of the requested information to the productive process is tangential at best . . . .").

169 5 U.S.C. § 522(b)(4).

170 *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).

171 *Id.* at 990.

for health and safety information submitted as part of the application.[172] Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which gave the EPA the authority to regulate the sale of pesticides.[173] In order to market a pesticide in the United States, a manufacturer must gain EPA approval,[174] which parallels the requirement that a generic manufacturer must have FDA approval in order to market a generic drug.

Monsanto, a company that developed and manufactured pesticides, submitted an application to the EPA for approval to market a new chemical.[175] Throughout the application process, Monsanto took special care to protect health and safety data that they used to test the chemical.[176] The company spent approximately $23.6 million in order to generate this information, and did not want the EPA to use it to test other chemicals.[177] Under the FIFRA statute, however, the EPA was allowed to use information submitted for the registration of a pesticide to evaluate subsequent applications, and the statute also allowed the EPA to publicly disclose some of the submitted information.[178] The statute was silent with regard to the disclosure of health and safety information, which the manufacturer was seeking to protect.[179] The stakes of the case were raised because like developing and marketing a generic drug,[180] manufacturing a pesticide requires expenditures of between five and fifteen million dollars annually over several years.[181] When the EPA tried to use and disclose Monsanto's health and safety information, the company sued, claiming that the EPA's use of its health and safety data constituted a taking and was prohibited under the Takings Clause of the Fifth Amendment.[182]

The Supreme Court asked whether Monsanto had a property interest in the health and safety data, and if it did, whether the EPA's use of the data

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[172] *Id.* at 998.

[173] 61 Stat. 163 (1947), *codified at* 7 U.S.C. §§ 136–136y (2012).

[174] *Ruckelshaus*, 467 U.S. at 991.

[175] *Id.* at 997–98.

[176] *Id.* at 998.

[177] *Id.*

[178] *Id.* at 990.

[179] *Id.* at 991.

[180] Although the cost of developing and manufacturing a generic drug is only about 15% of the price of developing and manufacturing a new, brand name drug (Facts about Generic Drugs, U.S. Food & Drug Admin., http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.html (last updated Sept. 19, 2012)), manufacturing a generic can still cost between $120–$150 million (*ABC News, Bitter Medicine: Pills, Profits and the Public Health*, ABC TELEVISION BROAD., May 29, 2002, LEXIS, News Library, Transcripts File).

[181] *Ruckelshaus*, 467 U.S. at 998.

[182] *Id.* at 1001; *see also* U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation.").

constituted a taking.[183] Because Monsanto asserted that the data was a trade secret, the Court chose the Restatement of Torts' definition of 'trade secret' for the purposes of deciding the case.[184] According to the Restatement, a trade secret is "any . . . compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."[185] The Court found that Monsanto did have a property right protectable by the Fifth Amendment in the data.[186] However, the Court also ruled that, "[A]s long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking."[187] In other words, because Monsanto was on notice during some of the relevant statutory period that the EPA could use the information to evaluate other chemicals and could subject it to public disclosure, the EPA's use of the information could not constitute a taking for the purposes of the Fifth Amendment. The Court further noted that some of the EPA's disclosure of health and safety information constituted a taking,[188] because Monsanto classified the submitted information as a trade secret, which, for a certain period before the statute was amended, was permitted.[189]

Ruckelshaus offers a lesson to generic drug manufacturers about the limits of the protection offered by trade secret law for their bioequivalency tests. So long as a bioequivalency test meets the appropriate requirements for a trade secret under the Restatement of Torts, a manufacturer has a property interest in the test.[190] This is important because if the test constitutes property, then some immunity against disclosure would apply, and the FDA will not have freedom to disclose the information to whomever asks. However, the holding of *Ruckelshaus* indicates that this exclusion right is not unlimited and that courts would likely be unsympathetic to a generic manufacturer who submitted information to the FDA knowing that the FDA was able to use and disclose certain information.[191] Thus, it is important for generic manufacturers to take precautions demonstrating the value of a bioequivalency test and its utmost

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183 *Ruckelshaus*, 467 U.S. at 1000.
184 *Id.* at 1001.
185 *Id.* (quoting RESTATEMENT OF TORTS § 757 cmt. b).
186 *Id.* at 1003–04.
187 *Id.* at 1007.
188 *Id.* at 1010.
189 *Id.* at 1011.
190 *Id.* at 1003–04.
191 *See id.* at 1007.

importance to the process of manufacturing a generic drug, as did the petitioner in *Ruckelshaus* with the health and safety information pertaining to its pesticide.

Section 20 of the Code of Federal Regulations is particularly instructive as to the FDA's rights to information submitted to it by generic drug manufacturers.[192] The FDA's policy is to make the fullest disclosure of information possible, except when the information falls into a protected category, one of which is a trade secret.[193] For this reason, it is important that drug manufacturers classify bioequivalency tests as trade secrets from the time of their first application for FDA approval. Furthermore, the court will often ascertain the actual value of submitted information by looking at the submitter's own efforts to protect it,[194] so generic manufacturers should take measures to protect the submitted information. For example, in *Ruckelshaus*, the Court noted, "Monsanto has instituted stringent security measures to ensure the secrecy of the data."[195] Thus, if generic manufacturers take steps to protect their bioequivalency tests from disclosure before the information is submitted to the FDA, this evidence of the tests' value would cut in favor of the manufacturer were the FDA to consider disclosure. While the *Ruckelshaus* Court noted that "the Trade Secrets Act is not a guarantee of confidentiality to submitters of data,"[196] classifying information as a trade secret *before* submitting the information to the FDA can offer the submitter greater protection.

3. Overcoming Potential Litigation-Related Threats of Disclosure Right of Public Access. In addition to the threats of disclosure posed by FOIA requests and FDA use of the information, litigation proceedings, and specifically discovery requests, pose a third potential threat of disclosure. For example, if a generic manufacturer were to be sued by a competitor or third party, the generic manufacturer will be concerned that a bioequivalency trade secret could be subject to disclosure through a discovery request. While the Federal Rules of Civil Procedure contain specific provisions to protect litigating parties from the disclosure of trade secrets during the discovery process,[197] generic manufacturers will want to take special precautions in order to receive full protection for their bioequivalency tests. Case law can additionally protect a

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[192] *See supra* notes 84–85 and accompanying text.
[193] *See supra* notes 85–104 and accompanying text.
[194] *Ruckelshaus*, 467 U.S. at 1002.
[195] *Id.* at 998.
[196] *Id.* at 1008.
[197] FED. R. CIV. P. 26(c)(1)(G); *id.* § 45(d)(3)(B).

generic manufacturer's bioequivalency tests from litigation-related threats of disclosure.[198]

The threat of trade secret disclosure posed by the discovery process can be very serious because of the common law right of public access.[199] As the court notes in *Nycomed*, "The courts have long recognized a common law right of public access to judicial documents."[200] The primary theory behind the doctrine of the right of public access is related to the desire for the general public to perceive the court as an independent and legitimate body.[201] The Second Circuit has noted, "The political branches of government claim legitimacy by election, judges by reason. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like fiat and requires rigorous justification."[202] Thus, courts are strict about maintaining public access to judicial documents in order to maintain legitimacy and provide information for the general public. However, the court's desire conflicts with a generic drug manufacturer's interest in keeping information about bioequivalency tests hidden.

If a trade secret cannot withstand the common law right of public access, trade secret protection is of little use to generic manufacturers who face a discovery request by an opposing party for documents containing information related to bioequivalency testing methods. Although the common law right of public access can make the process of protection tricky for generic manufacturers, generic manufacturers can use the Second Circuit's three part test to determine whether a judicial document should be susceptible to the common law right of public access[203] in order to argue against disclosure.

The Second Circuit has stated that when judicial documents are requested, the presumption is that they are susceptible to public access.[204] Courts do err on the side of disclosure, but the common law right of public access is not absolute.[205] The Second Circuit's test to determine whether a judicial document is subject to the common law right of public access, as mentioned previously, involves three steps[206]: "First, the court must determine whether the documents are indeed judicial documents . . . Second, if the documents are judicial

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198 *See, e.g.*, Nycomed US, Inc. v. Glenmark Generics, Inc., No. 08-CV-5023(CBA), 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.).

199 *Id.*

200 *Id.* at *7 (quoting Stern v. Cosby, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2006)).

201 *Id.*

202 *Id.* (quoting United States v. Aref, 533 F.3d 72, 83 (2d Cir. 2008)).

203 *See supra* notes 128–29.

204 *See* United States v. Amodeo, 71 F.3d 1044, 1047–49 (2d Cir. 1995).

205 *See* Nixon v. Warner Commc's, Inc., 435 U.S. 589, 598 (1978).

206 Stern v. Cosby, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007). *See also supra* notes 128–29.

documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it."[207]

It is likely that, were the situation to arise, a generic manufacturer could successfully argue that a bioequivalency test protected as a trade secret should not be susceptible to the common law right of public access under the Second Circuit's analysis.[208] Looking at the first factor—"whether the documents were judicial documents to which the public had a right of access"[209]—a manufacturer could likely end the inquiry here. The definition of "judicial documents," as discussed in Part II.C,[210] is "relevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings, [and] become documents to which the presumption of public access applies."[211] Thus, the only way that the definition would apply is if the documents with the relevant trade secret information were requested by or submitted to a court, which is not likely to be necessary unless the lawsuit concerns the bioequivalency testing method itself.

In addition, even if a court does request documents containing trade secrets, generic manufacturers could argue against disclosure based on the theory behind the common law right itself. For example, if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected, then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court's reputation. Inventors, manufacturers, and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks.

Turning to the second factor, "the weight of the presumption of disclosure,"[212] a generic manufacturer would again have a strong argument against disclosure. As the court notes, "[T]he weight of the presumption depends on the 'role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the

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[207] *Stern*, 529 F. Supp. 2d at 420 (quoted in Nycomed US, Inc. v. Glenmark Generics, Inc., 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.)) (internal quotation marks omitted).

[208] *See supra* notes 128–29.

[209] *See supra* notes 128–29.

[210] *See supra* note 127.

[211] Lugosch v. Pyramid Co. of Onondaga, 435 F.3d 110, 122 (2d Cir. 2006) (quoting FTC v. Standard Fin. Mgmt. Corp., 830 F.2d 404, 409 (1st Cir. 1987)).

[212] *Stern*, 529 F. Supp. 2d at 420.

federal courts.' "[213] In other words, due to the high value of a bioequivalency test being kept a secret from competing manufacturers, the presumption of disclosure by the court would not be high and would favor the position of a generic manufacturer. The court further states the inquiry is often based largely on whether the information sought to be disclosed is germane to the litigation, especially if the information is used for a motion to dismiss.[214] Thus, for the purposes of a generic manufacturer protecting a bioequivalency test, unless the test itself was of central importance to the litigation, the presumption would weigh in favor of nondisclosure. Furthermore, keeping in mind the purpose of the doctrine, it makes sense that the presumption is stronger when the information is related to a motion to dismiss, because if the court dismisses a case based on a motion, it needs to show good cause for the dismissal.

Finally, when looking at the third factor—competing considerations against the presumption[215]—it is likely that the generic manufacturer would be able to win the battle over disclosure at this step, if they could not do so via steps one or two. As mentioned above, if courts will disclose lucrative, competition-driving methods and formulas to the public during litigation, generic manufacturers seeking protection will not seek judicial remedies. Furthermore, a manufacturer's active and vigorous defense of a trade secret is itself evidence of its value. If public disclosure via the common law right of public access causes the generic manufacturer to lose its competitive advantage, as well as the millions of dollars it invested in development of the secret,[216] the presumption would favor disclosure. As demonstrated in *Momenta*, bioequivalency tests offer a competitive advantage to generic companies who develop them.[217] Because so much of the generic manufacturer's competitive advantage is stored in the bioequivalency test, the court would be reticent to subject this precious and valuable information to judicial disclosure.

For example, in *Nycomed*, the defendant sought to have the plaintiff's brief containing motions to amend the pleadings exempted from the common law right of public access, as the brief allegedly contained information that the defendant considered confidential.[218] Defendant Glenmark argued that because

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[213] Nycomed US, Inc. v. Glenmark Generics, Inc., No. 08-CV-5023(CBA), 2010 U.S. Dist. LEXIS 20788, at *9 (E.D.N.Y. 2010) (quoting United States v. Amodeo, 71 F.3d 1044, 1049 (2d Cir. 1995)) (internal citations omitted).

[214] *Id.*

[215] *Id.* at *8.

[216] *See, e.g.*, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1351 (Fed. Cir. 2012).

[217] *Id.*

[218] *Nycomed*, 2010 U.S. District LEXIS 20788, at *12.

26(c)(1)(G) to prevent a party from having to disclose a trade secret during the discovery stage of litigation.[226] The plaintiff, Massey Coal, sued defendant, Victaulic, for various counts of breach of contract and misrepresentation.[227] The defendants manufactured and installed piping that the plaintiff used in its coalmines; when the pipes failed, the defendants admitted there was a problem but would not provide further information.[228] Before the hearing, the judge issued a protective order for "documents or other materials . . . subject to disclosure . . . [that are] confidential and should not be disclosed other than in connection with this action."[229] The defendant disclosed to the plaintiffs several documents marked 'CONFIDENTIAL' per the protective order, a few of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail. Because the pipes were used to carry drinking water throughout the county, the plaintiffs made a motion to disclose the information to the Public Service Authority.[230] The defendant objected, invoking protection from Rule 26(c)(1)(G)[231] and arguing that the documents contained commercially valuable information.[232] For the purposes of analysis, the court noted that Rule 26(c)(1) "treats equally a trade secret or other confidential commercial information."

Ultimately, the trial judge held that the documents were not protectable via Rule 26(c)(1),[233] but the reasoning of the court is helpful in understanding the scope of the protection offered under 26(c)(1). In order to get a protective order for discovered documents under 26(c)(1), the party possessing the documents must show "good cause" for protection, including, most relevantly, "undue burden or expense."[234] Essentially, the defendants in this case argued that "severe economic damage" would result from disclosure.[235] However, the court noted, "Broad allegations of harm, unsubstantiated by specific examples . . . do not satisfy the Rule 26(c) test. Moreover, the harm must be significant, not a mere trifle."[236] Additionally, the court stated that the

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226 Massey Coal Servs., Inc. v. Victaulic Co. of Am., 249 F.R.D. 477 (S.D.W. Va. 2008).
227 *Id.* at 478.
228 *Id.*
229 *Id.* at 479.
230 *Id.*
231 *Id.* at 482 (internal quotations omitted) (internal citations omitted).
232 *Id.*
233 *Id.* at 484.
234 *Id.* at 480; Cipollone v. Liggett Grp., Inc., 785 F.2d 1108, 1121 (3d Cir. 1987) (addressing the "standard for determining whether [d]efendants have shown good cause for a protective order" (citations omitted))). *See also* FED. R. CIV. P. 23(c)(1); *supra* text accompanying note 134.
235 *Massey Coal Servs., Inc.*, 249 F.R.D. 477.
236 *Id.* at 481 (citation omitted).

defendants had made no showing that they had undertaken efforts to keep the documents a secret,[237] that the defendants had not objected to disclosure of the documents to the plaintiffs, that the documents were contained in the court's public record, and that the defendants did not file a motion to seal the documents.[238] In light of these facts, the court reasoned that the documents were not commercially valuable and were not protectable.[239] The trial judge further stated that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants, the embarrassment was not a concern of the court and would not protect the documents from disclosure.[240]

In light of the *Massey* court's holding and reasoning, if a generic manufacturer protecting a bioequivalency test via trade secret law wishes to prevent disclosure via Rule 26(c)(1), it must show "good cause" for a protective order by demonstrating "undue burden or expense."[241] The manufacturer should provide the court with "specific examples or articulated reasoning"[242] that disclosure of the trade secret would cause substantial economic harm to the manufacturer. Further, the manufacturer should show that this harm will be significant, and "not a mere trifle."[243] Generic manufacturers should also consider factors commonly used to measure secrecy, found in the Restatement of Torts. Such factors can include:

> [T]he extent to which the information is known by employees and others involved in the business . . . the extent of measures taken by the business to guard the secrecy of the information . . . the value of the information to the business and to its competitors . . . and the amount of effort or money expended in developing the information.[244]

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237 *Id.* at 483.
238 *Id.* at 484.
239 *Id.* at 482–83.
240 *Id.* at 484.
241 *See* Cipollone v. Liggett Grp., Inc., 785 F.2d 1108, 1121 (3d Cir. 1987); *see also* FED. R. CIV. P. 26(c)(1).
242 *Cipollone*, 785 F.2d at 1121.
243 *Id.*
244 *Massey Coal Servs., Inc.*, 249 F.R.D. at 482.

Again, since bioequivalency tests take substantial time, effort, and funding to create, they are critical to a generic manufacturer's market competitiveness.[245] Therefore, the manufacturer should take great care in maintaining their secrecy, for example, by limiting the number of employees who have the formulas, making employees sign confidentiality agreements and covenants not to compete, and maintaining a financially reasonable amount of computer system security. If a generic manufacturer is sued, it should be fairly simple to demonstrate to the court that documents containing the specific bioequivalency formula should either not be disclosed because they are not germane to the lawsuit, or that they should be privileged and confidential due to their economically valuable nature.

In addition, Rule 45 of the Federal Rules of Civil Procedure,[246] which governs subpoenas, could also benefit a generic manufacturer seeking to protect a bioequivalency test through trade secret law during litigation. A generic manufacturer's bioequialency test trade secret will lose its value if disclosed; given the test's high value, generic manufacturers will want to be aware of the risk of being subpoenaed so that they can demonstrate, if necessary, why a bioequivalency test trade secret should not be disclosed. When determining whether or not to quash a subpoena that could potentially pose a threat of disclosure to a generic manufacturer's bioequivalency test trade secret, the court will balance the burden of disclosure with the potential need/use of the information.[247]

Although there is also no per se protection for trade secrets under Rule 45, it is likely that a generic manufacturer would be able to withstand disclosure of a bioequivalency test in the event of a subpoena. For example, *In re Fosamax* demonstrates that drug manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure. A group of plaintiffs sued defendant drug company, Merck & Co., alleging that a drug they manufactured, Fosamax, caused adverse side effects.[248] The plaintiffs issued a subpoena to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the direction of the FDA.[249]

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[245] *See* Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1351–52 (Fed. Cir. 2012); Teva Pharm. USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y. July 16, 2013).

[246] FED. R. CIV. P. 45.

[247] *See supra* notes 138–41 and accompanying text.

[248] *In re* Fosamax Prods. Liab. Litig., No. 1:06-MO-1789(JFK)(JLF), 2009 U.S. Dist. LEXIS 70246, at *26 (S.D.N.Y. Aug. 4, 2009).

[249] *Id.* at *28.

Dr. Psaty moved to quash the subpoena under Rule 45(d)(3)(B),[250] alleging that he never studied the drug in question;[251] furthermore, the defendant urged that even if Dr. Psaty testified, it was unclear whether he would be required to disclose confidential information or trade secrets.[252] In making its decision, the court tried to balance the burden between necessity of the testimony and the undue burden on the defendant to produce the information, ultimately quashing the subpoena.[253] In considering whether there is an undue burden on the defendant, the court assesses the personal hardship to the party protecting the information and the wider social consequences of disclosing the information.[254] Here, the court noted that if Dr. Psaty were required to testify, "the resulting social impact would be far more serious. Compelling testimony from a third party researcher risks chilling participation in beneficial public research."[255] Thus, the court recognized the value of trade secrets, suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them.

When comparing this case with the potential disclosure of a generic manufacturer's bioequivalency test, generic manufacturers who receive subpoenas would likely not be required to disclose trade secrets if called to testify. Even if the testimony sought were important to the case, the balancing of the burden between necessity of the testimony and the undue burden placed on the defendant would likely weigh in favor of quashing the subpoena. The personal hardship to the generic manufacturer would be catastrophic, resulting in the loss of millions of dollars in profits or the loss of commercial market advantage.[256] In addition, the consideration of wider social impact would weigh in favor of suppressing the subpoena, because requiring generic drug manufacturers to disclose trade secrets could have a chilling effect on beneficial scientific research.

Generic manufacturers provide a valuable service to consumers by lowering the cost of drugs. However, because the Federal Circuit's expansive reading of

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[250] *Id.* at *27. *See also* FED. R. CIV. P. 45(d)(3)(B)(i)–(ii) ("To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information; or (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.").

[251] *In re* Fosamax Prods. Liab. Litig., 2009 U.S. Dist. LEXIS 70246, at *28.

[252] *Id.* at *30.

[253] *Id.* at *33–34.

[254] *Id.* at *34.

[255] *Id.* at *35.

[256] *See, e.g.*, Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348 (Fed. Cir. 2012).

two paragraphs of the plaintiff's motion contained confidential information related to Glenmark's ANDA, this information was exempt from public disclosure.[219] The court, however, disagreed. This situation is easily distinguishable from the hypothetical situation in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a bioequivalency test protected via trade secret law, because information protected as trade secret would not be found in an opposing party's brief to start with, if it was actually a secret. In *Nycomed*, the defendant sought to protect information contained in the plaintiff's brief; surely an opposing party's motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place, if the alleged trade secret were really a secret. After reviewing the FDA's relevant provisions regarding the disclosure of pending ANDA's, the court notes, "Certainly, any information that is already public, or is independently made public, cannot be deemed confidential."[220] The court also noted that the FDA's regulations guarded only against disclosure by the FDA and not the common law right of public access.[221] Thus, so long as the generic manufacturer actually treats the bioequivalency test information allegedly within the scope of the common law right of public access as a legitimate secret, the presumption against disclosure during litigation should cut in favor of the generic manufacturer.

In addition to the potential for disclosure due to a competitors assertion of the common law doctrine of public access during litigation, the discovery rules could also pose a legitimate threat to generic manufacturers who seek to protect their bioequivalency tests. As several cases have noted, there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil Procedure.[222] However, many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during discovery.[223] Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss 'trade secrets,'[224] and often work together to protect parties from disclosure.[225]

In *Massey Coal Services, Inc.*, for example, the court explained the circumstances under which a court can issue a protective order pursuant to Rule

p.13

p.13

p.14

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[219] *Id.* at *15.
[220] *Id.* at *16.
[221] *Id.*
[222] Paulsen v. Case Corp., 168 F.R.D. 285, 289 (C.D. Cal. 1996).
[223] Hamilton v. State Farm Mut. Auto. Ins. Co., 204 F.R.D. 420, 422 (S.D. Ind. 2001).
[224] *See* FED. R. CIV. P. 26, 45; *see also* text accompanying notes 131–36 for a review of rules 26 and 45.
[225] *See generally In re* Fosamax Prods. Liab. Litig., No. 1:06-MO-1789(JCF), 2009 U.S. Dist. LEXIS 70246, at *30 (S.D.N.Y.).

the safe harbor provision in *Momenta v. Amphastar* gives generic manufacturers little protection for their bioequivalency tests through patent law,[257] the incentive to produce generic drugs will likely decrease if another method of protection is not found. Although trade secret law does not provide per se protection from disclosure,[258] generic manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests, FDA use of the information, and litigation.

Although FOIA encourages the broad disclosure of government-held information, a generic manufacturer can demonstrate to the FDA's FOIA office that bioequivalency test trade secrets are immune from disclosure. The generic manufacturer can point to the definition of trade secret adopted in *Public Citizen Health* to argue that a bioequivalency text qualifies as a trade secret, exempting it from disclosure. Generic manufacturers can also overcome the threat of disclosure posed by the FDA's potential use or disclosure of the information, because the FDA is only allowed to disclose protected information submitted to it by a third party under limited circumstances. Because generic manufacturers have a property interest in their bioequivalency test trade secrets, the FDA has a limited amount of power to disclose this information; so long as a generic manufacturer treats the bioequivalency test as a trade secret, the threat of disclosure by the FDA is manageable. Finally, litigation-related threats of disclosure, specifically the common law right of public access and discovery requests made by parties to a litigation, can also be overcome by generic manufacturers. The test developed by the Second Circuit in *Stern v. Cosby* can be used to show that the presumption in favor of disclosure present in the common law right of public access can be avoided by generic manufacturers protecting bioequivalency tests as trade secrets. Furthermore, generic manufacturers could also protect their bioequivalency test trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45. This Note has therefore demonstrated that generic manufacturers could successfully protect their bioequivalency research and development investments from use by competitors through the use of trade secret law.

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[257] *Id.* at 1361.

[258] United States v. Int'l Bus. Mach. Corp., 67 F.R.D. 40, 42 n.1 (S.D.N.Y. 1975) (holding that "trade secrets and other confidential commercial information enjoy no privilege from disclosure although courts may choose to protect such information").

IV. CONCLUSION

Altogether, this Note has explored the impact and the consequences of the recent holding in *Momenta* and one potential solution to the problems created by the Federal Circuit.[259] The *Momenta* majority held that a generic manufacturer who uses the patented bioequivalency test of a competitor is protected from liability by way of the safe harbor provision of the Hatch Waxman Act.[260] As Chief Judge Rader points out in his dissent, the majority's holding effectively renders all patents on bioequivalency testing methods worthless,[261] an effect confirmed by later proceedings.[262] In light of the *Momenta* holding, generic manufacturers are now in need of a way to protect their bioequivalency testing methods from use by their competitors. This Note has demonstrated that trade secret law can provide a viable alternative to patent protection for generic manufacturers, at least in the absence of any action by Congress to address the Federal Circuit's expansive reading of the safe harbor provision in *Momenta v. Amphastar*.

Generic manufacturers can protect their bioequivalency tests through trade secret law by overcoming obstacles in three potentially threatening contexts. Generic manufacturers can overcome the threat of disclosure from a FOIA request by arguing that bioequivalency tests fit within the scope of the definition of "trade secret" and constitute commercially valuable information. Second, generic manufacturers can withstand the threat of disclosure through the FDA's own use of the information by again arguing that a bioequivalency test constitutes a trade secret, under the specific FDA definition and by showing positive steps taken to treat the information as a secret, meeting the Second Circuit's test. Third, generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution, and that this purpose would be defeated if the court disclosed a manufacturer's extremely valuable information to competitors. Finally, generic manufacturers can use trade secret law to protect bioequivalency tests despite the threat of disclosure from litigation by invoking Federal Rules of Civil Procedure 26(c) against discovery requests for documents and Rule 45 against subpoenas.

Ideally, Congress will recognize the Federal Circuit's unfortunate holding in *Momenta* with corrective legislation to restore the power of patent protection to

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259 Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1368 (Fed. Cir. 2012).
260 *Id.* at 1361.
261 *Id.* at 1362 (Rader, J., dissenting).
262 *See* Teva Pharm. USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.).

generic manufacturers. However, in the meantime, or indefinitely into the future if necessary, trade secret law can provide an alternative to patent protection for generic manufacturers who desire to protect their bioequivalency tests from the hungry eyes of their competitors.

EXHIBIT G

Williams, Laura H

From: Williams, Laura H
Sent: Monday, January 3, 2022 5:40 PM
To: Tshudy, Trisha R
Cc: Sondhi, Sabrina
Subject: Honor Code
Attachments: Honor-Code Revision 12.2.2020 FINAL.pdf

Importance: High

Hi Trisha-
Thanks for talking with Prof. Sondhi and me this afternoon.

The Honor Code can be found here: https://dickinsonlaw.psu.edu/honor-code#1.1. In the event you have trouble accessing it, I have attached a copy. If you have any questions about the Honor Code, please let me know.

I will need your information ASAP. This is a very important matter. Thanks for your understanding.
Dean Williams

Laura H. Williams
Associate Dean for Administration
Dickinson Law
The Pennsylvania State University
150 S. College St.
Carlisle, PA 17013
717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

EXHIBIT H

Williams, Laura H

From: Williams, Laura H
Sent: Tuesday, January 4, 2022 5:06 PM
To: Tshudy, Trisha R
Subject: RE: Honor Code
Attachments: Scanned Tshudy paper with highlighting.pdf; Scanned Rogers Note with highlighting.pdf

Dear Trisha-
Thank you for your note.

While your explanations are helpful, they do not explain how or why your paper is so similar to this Note published in 2014 in the Journal of Intellectual Property Law: Hannah-Alise Rogers, *Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar*, 22 J. Intell. Prop. L. 209 (2014).

I noticed that you copied large sections of Ms. Rogers' Note into your outline. Similarly, large sections of this Note were copied into your final paper, many of them verbatim, or with only limited modifications. You do not, however, cite to Ms. Rogers' Note anywhere in your final paper.

Definition:
The Dickinson Law Honor Code Section 1.1 defines Plagiarism as follows:

> "(L) Plagiarism: Should be given its usual dictionary meanings: to steal and pass off (the ideas or words of another) as one's own; to use (a created production) without crediting the source or to commit literary theft, presenting as new and original an idea or product derived from an existing source. Plagiarism includes the copying or paraphrasing without acknowledgment of any material written or expressed by another person, and the submission of work written in whole or in substantial part by someone other than the student who submits the work as the student's own work. Plagiarism also includes the re-submission of work originally completed for another course and the giving or receiving of excessive assistance or making excessive use of the work of someone else in preparing an assignment, without faculty approval. What constitutes "excessive assistance" or "making excessive use of the work of someone else" is a matter for the course professor to decide and communicate in a timely manner to the students. Unless the course professor gives different instructions, "excessive assistance" should be construed with reference to the academic purpose of the assignment - to develop the student's research and writing skills and to evaluate his or her skills. A student may receive some counsel and suggestions from other people, e.g., another student, the course professor, so long as the paper is, in both pedagogical and literary senses, the work of the student."

Review:
I have attached your paper, highlighted with all the places that the words in your paper match those in Ms. Rogers' Note, in many cases word-for-word. Similarly, I have attached Ms. Rogers' Note, highlighted with all the places that your paper directly lifts sections this Note.

1) It appears to me that you have attempted to pass off both the ideas and the words of Ms. Rogers for your own in direct contravention of the Dickinson Law Honor Code. Your paper tracks the Analysis section of Ms. Rogers work directly. You present the same ideas, in the same order, using (in most instances) the same words.

2) Furthermore, you used a published work without crediting the source, also a violation of the Honor Code.

3) In some instances, you paraphrased Ms. Rogers' work or re-ordered sentences, but the words and the ideas are the same, again without any attribution to Ms. Rogers' work.

You have explained to me that as you delved into the subject matter, you determined that the subject matter of your paper was not unique. In your paper, you have cited to the original sources. That does not, however, exonerate you from using someone else's analysis of these original sources, much less their unique order of words and phrases.

Process:
Section 5.1 of the Honor Code provides that "[A]any person affiliated with the law school may report a violation by submitting a memorandum to the Honor Code Administrator…" As you know, in my role as Honor Code Administrator, I received a report of suspected violation from Prof. Gould.

Section 5.2 provides that as Honor Code Administrator, I was obligated to meet with you "as soon as practicable" after receiving the report, which is what prompted my call to you yesterday. This section goes on to say that the Honor Code Administrator and the student can resolve matters by written agreement. In the absence of an agreement, the Honor Code Administrator is obligated to meet with the Honor Committee Chair (defined in Section 1.1 (H)) to determine whether the matter should proceed to a Hearing.

If you would like to make a Conscientious Admission (defined in Section 1.1(E)), we can resolve this matter by Agreement. Making a Conscientious Admission does not necessarily mean that the consequences for the violation will be less onerous than if there is a hearing (see the sanctions in Chapter 6).

If we do not reach an agreement, based on what I have seen, and based on my conversations with Prof. Gould, I will recommend to the Honor Committee Chair that we proceed with a Hearing.

As we have discussed, this is a very serious matter. Please let me know how you would like to proceed no later than 5 PM tomorrow, Wednesday, January 5, 2022.

With kind regards,
Dean Williams

Laura H. Williams
Associate Dean for Administration
Dickinson Law
The Pennsylvania State University
150 S. College St.
Carlisle, PA 17013
717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

From: Tshudy, Trisha R <trt5096@psu.edu>
Sent: Tuesday, January 4, 2022 3:48 PM
To: Williams, Laura H <lhw10@psu.edu>
Subject: Re: Honor Code

Dear Dean Williams,
Professor Gould gave a sample paper for the class to see what was expected. Within that sample paper, the only references and resources that were cited were only the ones directly referred to and not any that were read,

researched, or considered when creating the overall piece. It was given as an example to follow. The only difference or variation I made with formatting my own off of the example given was listing my references at the end of my paper instead of at the bottom of each page. I did so because I was having issues with formatting as well as being able to track word count and maintain readability with each page being dually devoted to content and citation. Let me know if you would like me to attach a copy of it. I did download it and save it to my class folder so I could work on my own research paper while I was offline. Thank you so much for your time.
With Much Appreciation,
Trisha Tshudy

Get Outlook for iOS

From: Williams, Laura H <lhw10@psu.edu>
Sent: Tuesday, January 4, 2022 2:26:39 PM
To: Tshudy, Trisha R <trt5096@psu.edu>
Subject: RE: Honor Code

Hi Trisha-
Thanks for your note.
In "Section III. Trade Secret Law and the Potential Threats of Disclosure: Emerging Issues as Reflected in Litigation" of your outline you say: "This entire section is repeated across so many articles, papers, and trade secret litigation advertisements that I followed the sample paper example and included the resources that I specifically drew from."

To what "sample paper example" are you referring?
Dean Williams

From: Tshudy, Trisha R <trt5096@psu.edu>
Sent: Tuesday, January 4, 2022 12:02 PM
To: Williams, Laura H <lhw10@psu.edu>
Subject: Re: Honor Code

Dear Dean Williams,
So far without even using Lexus and Westlaw, I have culminated a list of 33 papers/articles/analyses/etc. that directly align with the information in mine. I wanted to send some of them over so you can start to get an idea of how written about this topic has become. If you can provide me a narrower view of what part of my paper is exactly in question, I can help reduce the sources for your viewing purposes or even direct you to more specific ones since I have no idea which would be question. I am also attaching my refined outline where Professor Gould advised me on what specific direction, he wanted me to go as well as quite a few other particulars. I also wrote in a few responses while I am trying to determine what section is in question. Nearly the entire second section was based on class work, and I explained that I did write analyses and responses to Professor Gould for participation credit, but that those were just a backup if we had technical difficulties, so it was my in-class presentation that counted. Therefore, I do not believe that is considered a violation from multiple submissions of my same observations, because it only counted once. The second section is even more common and generic whether it's just going through rules of civil procedure applying to trade secrets or even when it receives the added specificity of the biotech/pharmaceutical lens that Professor Gould specified was necessary. Unlike the first section where those cases were read in class, the cases in the second section were ones that were commonly cited and reiterated when explaining the implications. The analysis for the three-part test alone is covered by a multitude of articles. Therefore, to prevent getting bogged down, I went

directly to the cases themselves and important takeaways, headnotes, and quotes that I am sure everyone else recognizes and pulls out as well. Again, I am happy to continue working, but if there is a way to narrow down what is in question, that would be much appreciated because again, I can come up with well over thirty resources immediately that I can find comparable sections or organization with on the exact topic. Also, let me know if you would like information on who I specifically talked to regarding my concerns and the feeling that Professor Gould really commandeered my topic selection into one that I had no idea was written about so extensively and comprehensively. I can also list the steps I took to try to prevent any issue since it was a slight concern of mine. Moreso, I was concerned about making sure my resource list was cited correctly, but I would be surprised if there is any student who fears an accusation of an honor code violation. Even earlier this semester for my unincorporated business class, Professor Prince thought I had copied on an assignment until I showed her that the reason it was so unique was because it was about a real-life example of my friend who is a falconer that I used as inspiration. I even prepared my internet history and everything to show her that I didn't even glance at a comparable resource. I took my knowledge of her story and Professor Prince's PowerPoint (simply to make sure the hypo I created was covered) but apparently it was too entrepreneurial that she thought it was copied before I sent her everything, she needed to confirm without a doubt that I did not. Anyway, I'll keep working and look for your response. Again, there are so many that overlap, and I read so extensively prior to topic selection and then refinement by Professor Gould that I can easily show multiple sources that took the exact path of organization since that is literally what the emerging doctrine entails. But again, it is all in my own words and everything that ties to a specific article or statute is cited. Thank you so much for your time.

With Much Appreciation,

Trisha Tshudy

1. Robert Graham Gibbons, Bryan J. Vogel, The Increasing Importance of Trade Secret Protection in the Biotechnology, Pharmaceutical and Medical Device Fields, 89 J. Pat. & Trademark Off. Soc'y 261, 285 (2007)

2. Drugmakers, pharma groups ask justices to end 'blocking patent' doctrine, 2019 WL 2147798

3. § 4:23. Patenting vs. maintenance as a trade secret, 1 Pat. L. Fundamentals § 4:23 (2d ed.)

Three cases that also came up, but because they were written about so much and I had the option of using the cases from class, that I would just use those instead. But these are the three….

1) Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 189 L. Ed. 2d 296, 110 U.S.P.Q.2d 1976 (2014). *See* §§ 7:5 & 20:119, *infra*.

2) Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1296–98, 182 L. Ed. 2d 321, 101 U.S.P.Q.2d 1961, 1967–69, 90 A.L.R. Fed. 2d 685 (2012). *See* § 7:4.50, infra.

3)Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116–19, 186 L. Ed. 2d 124, 106 U.S.P.Q.2d 1972, 1979–81 (2013). *See* § 7:4.50, infra.

4. Northrop, Protecting Software: The Trade Secret or Patent Decision Tree, 88 Pat., Trademark & Copyright J. 222 (May 16, 2014); Bason, Intellectual Property/Trade Secrets: Panelists Say Alice, AIA Among Factors Driving Would-Be-Patentees to Trade Secrets, 89 Pat., Trademark & Copyright J. 686 (Jan. 16, 2015); Jeffrey Mordaunt & Joshua Swedlow, *Why Trade Secret Litigation Is On The Rise*, Law 360, Nov. 4, 2017.

5. Hannah-Alise Rogers, Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar, 22 J. Intell. Prop. L. 209, 214 (2014)

6. John T. Aquino, *Trade Secrets/Biotechnology: Attorney Says Federal Trade Secret Law May Better Protect Biotech Processes*, 91 Pat., Trademark & Copyright J. 1811 (Apr. 22, 2016).

7. Trade Secrets Protection in the Pharmaceutical Industry: Exploring Best Practices https://knowledgewebcasts.com/know-portfolio/protection-in-the-pharmaceutical-industry-cle/

8. https://www.winston.com/images/content/2/0/v2/203824/trends-in-trade-secret-litigation-report-2020.pdf

9. APPENDIX III -- FDA PREAMBLE, GUIDANCE AND OTHER ADVISORY DOCUMENTS, 2006 WL 3436684 (FDA info on requests, but did not go into specificity or use any ideas concepts or quotes that were specifically presented. It was simply background.)

10. Trends in Trade Secret Litigation Report 2020 https://www.stout.com/en/insights/report/trends-in-trade-secret-litigation-report-2020?gclid=Cj0KCQiA_c-OBhDFARIsAIFg3ew-zEfrAdl3FOnNxQPoFYm-AxG1fzV10T7-XKbXxF5dUP2CDORdxZ4aAmcNEALw_wcB

11. Trade Secrets in Life Science and Pharmaceutical Companies https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382727/(Contains all the background info on legislation and trade secret definitions. Unfortunately, the cases supplied dealt with misappropriation which Professor Gould did want me to concentrate on because it could be assumed to be known or wasn't worth analysis.)

12. Biotechnology and Trade Secret Protection https://www.robinskaplan.com/-/media/pdfs/publications/biotechnology-and-trade-secret-protection.pdf?la=en

13. The Curious Cases of Trade Secret Identification https://www.arnoldporter.com/-/media/files/perspectives/publications/2021/05/the-curious-cases-of-trade-secret-identification.pdf

14. All About What Constitutes Trade Secrets: Are Documents In Discovery Necessary?

by Romy Jurado | Mar 12, 2021 | Business https://jflawfirm.com/all-about-what-constitutes-trade-secrets-are-documents-in-discovery-necessary/

15. An Epic Trade Secret Mistake? Why Third Parties to Litigation May be at Risk of Losing Trade Secret Protections June 7, 2021By Carolyn Wimbly Martin and Robert Piper https://www.lutzker.com/an-epic-trade-secret-mistake-why-third-parties-to-litigation-may-be-at-risk-of-losing-trade-secret-protections/

16. North America: Discovery in Trade Secret Cases https://www.globalcompliancenews.com/2021/04/01/north-america-discovery-in-trade-secrets-cases-11032021/

17. Trade Secret Identification: Prerequisite to Discovery March/April 2015 IP Litigator By John F. Hornick; Margaret A. Esquenet https://www.finnegan.com/en/insights/articles/trade-secret-identification-prerequisite-to-discovery-1.html

18. Discovery of Trade Secrets Santa Clara Law Journal https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1152&context=chtlj

19. Trade Secrets: 10 Keys to Successful Litigation by Jessica Brown and Tafari Lumumba https://www.gibsondunn.com/wp-content/uploads/documents/news/Brown-Lumumba-Trade-Secrets-10-Keys-to-Successful-Litigation-Colorado-Lawyer-Jan.-2016.pdf

20. The "Attorneys' Eyes Only" Designation and Other Disclosure Restrictions in Trade Secrets Litigation https://frostbrowntodd.com/the-attorneys-eyes-only-designation-and-other-disclosure-restrictions-in-trade-secrets-litigation/

21. Loss of Trade Secrets through Inadvertence https://cyber.harvard.edu/openlaw/DVD/research/EFF_General_8.html

22. Life, Liberty, and Trade Secrets 70 STAN. L.REV. 1343 (2018) https://review.law.stanford.edu/wp-content/uploads/sites/3/2018/06/70-Stan.-L.-Rev.-1343.pdf (Discovery, Subpoenas, Protective orders, sealing, and courtroom closures, The Trade Secret Privilege Overprotects Intellectual Property, Substantive trade secret law, The purposes of trade secret law, Innovation concerns, The Scope and Purpose of Privilege Law, Judicial authority and a criminal trade secret privilege, Sensitive information inside and outside the courts)

23. Trade Secrets Challenges for Patent Prosecutors and Litigators https://www.stoel.com/legal-insights/article/trade-secrets-challenges-for-patent-prosecutors-an

24.Protecting Trade Secrets Disclosed To The FDA By Douglas Nemec, William Casey and Tara Melillo (February 13, 2018, 10:50 AM EST) file:///C:/Users/ttshu/Downloads/Protecting_Trade_Secrets_Disclosed_to_the_FDA.pdf

25. Protecting Trade Secrets in the Medical Product Approval Process by Kristan Lansbery https://www.fdli.org/2018/04/update-protecting-trade-secrets-medical-product-approval-process/

26. Protecting Trade Secrets in the Pharmaceutical Industry in the Age of COVID-19 by Julie McCarthy https://www.seyfarth.com/dir_docs/publications/ProtectingTradeSecretsinthePharmaceuticalIndustryintheAgeofCOVID-19.pdf

27. Tips for Ensuring Your Competitors Do Not Steal the Valuable Fruits of Your Research and Development By Katherine Perrelli on March 28, 2014 https://www.tradesecretslaw.com/2014/03/articles/trade-secrets/tips-for-ensuring-your-competitors-do-not-steal-the-valuable-fruits-of-your-research-and-development/

28. The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines by Christopher J. Morten* and Amy Kapczynski**

https://29qish1lqx5q2k5d7b491joo-wpengine.netdna-ssl.com/wp-content/uploads/2021/04/3-Morten-and-Kapczynski-postEIC.pdf

29. Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 Marq. Intellectual Property L. Rev. 33 (2014).
Available at: https://scholarship.law.marquette.edu/iplr/vol18/iss1/1

30. McGarity, Thomas O., and Sidney A. Shapiro. "The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies." *Harvard Law Review*, vol. 93, no. 5, The Harvard Law Review Association, 1980, pp. 837–88, https://doi.org/10.2307/1340420.

31. Comments on Food and Drug Administration Transparency Task Force; Public Meeting and Request for Comments; Docket No. FDA-2009-N-0247; 74 Fed. Reg. 26,712 (June 3, 2009).
https://www.fdanews.com/ext/resources/files/archives/f/FDA-2009-N-0247-0107.1.pdf

32. DETERRING FRAUD: MANDATORY DISCLOSURE AND THE FDA DRUG APPROVAL PROCESS LIORA SUKHATME* https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-82-4-Sukhatme.pdf

33. Intellectual Property Protection for Biologics Megan Brewster
https://repository.upenn.edu/cgi/viewcontent.cgi?article=1035&context=ace

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From: Williams, Laura H <lhw10@psu.edu>
Sent: Monday, January 3, 2022 5:39 PM
To: Tshudy, Trisha R <trt5096@psu.edu>
Cc: Sondhi, Sabrina <szs7112@psu.edu>
Subject: Honor Code

Hi Trisha-
Thanks for talking with Prof. Sondhi and me this afternoon.

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I will need your information ASAP. This is a very important matter. Thanks for your understanding.
Dean Williams

Laura H. Williams
Associate Dean for Administration
Dickinson Law
The Pennsylvania State University
150 S. College St.
Carlisle, PA 17013
717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

EXHIBIT I

PennState Dickinson Law

Notice of Honor Code Proceeding

To: Trisha Tshudy

From: N.B. , Honor Committee Chair

Re: Notice of Hearing – **Friday, January 14, 2022, 1:00 PM**
Penn State Dickinson Law
150 S. College Street, Carlisle PA
Room 106 (Hearing Room)

Date: January 6, 2022

You have been accused of violating the Dickinson Law Honor Code. Under Section 5.3(A) of the Honor Code, I am giving you the following notice:

Alleged Violation
Biotech, Pharmaceuticals & the Law (Cert 997) – Prof. James Gould

Under Section 5.2(C) of the Honor Code, we have determined that probable cause exists to believe the following violations of the Honor Code may have occurred:

> 2.1(D) Violating any other rules of Dickinson Law or a member of its faculty pertaining to the administration of examinations or the completion of course work.
>
> 2.1(F) Violations of academic integrity. Violations of academic integrity include, but are not limited to, copying, Plagiarism, fabrication of information or citations, facilitation of acts of academic dishonesty by others, unauthorized possession of examinations, submitting work of another person or work previously used without informing the instructor, and tampering with the academic work of other students.

Hearing
A Hearing Board has been convened in accordance with Section 5.3(A) of the Honor Code. **The Hearing will be held on Friday, January 14, 2022 at 1:00 PM Room 106 (the Dickinson Law Hearing Room).**

Rights of the Accused Student & Hearing Procedures
The rules governing your rights can be found in Chapter Three of the Honor Code; The rules governing the Procedures for an Honor Proceeding can be found in Chapter Five.

Questions
Questions may be directed to me, or to Associate Dean Laura Williams, Honor Code Administrator.

EXHIBIT J

Williams, Laura H

From: Williams, Laura H
Sent: Monday, January 10, 2022 4:10 PM
To: Tshudy, Trisha R
Cc: N.B.
Subject: RE: Required Information for Honor Code Hearing - 1/14/22
Attachments: Biotech Pharmaceuticals & the Law Course Policies FA 2021.pdf

Dear Trisha-
Here is one additional document for Friday's Honor Code Hearing:

- BPL Course Policies – FA2021

Once again, if you have questions, please let me know.
Dean Williams

From: Williams, Laura H
Sent: Friday, January 7, 2022 12:21 PM
To: Tshudy, Trisha R <trt5096@psu.edu>
Cc: N.B.
Subject: RE: Required Information for Honor Code Hearing - 1/14/22

Dear Trisha-
Just to be clear, in addition to the documents listed below, I will be using the documents that I sent you on January 4, attached hereto.

- Your paper, marked to show the places that it tracks Ms. Rogers' Law Review Note; and
- Ms. Rogers' Law Review Note, marked to show how your paper corresponds with it

My apologies if this was unclear from my note below.

Thank you.
Dean Williams

Laura H. Williams
Associate Dean for Administration
Dickinson Law
The Pennsylvania State University
150 S. College St.
Carlisle, PA 17013
717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

From: Williams, Laura H
Sent: Friday, January 7, 2022 11:32 AM
To: Tshudy, Trisha R <trt5096@psu.edu>

Cc: N.B.
Subject: Required Information for Honor Code Hearing - 1/14/22

Dear Trisha:

As we discussed on Wednesday, January 5, the process for Honor Proceedings under the Dickinson Law Honor Code are provided in Chapter 5 of the Honor Code.

Section 5.1 of the Honor Code provides that "[A]any person affiliated with the law school may report a violation by submitting a memorandum to the Honor Code Administrator..." As you know, in my role as Honor Code Administrator, I received a report of suspected violation from Prof. Gould.

Section 5.2(A) provides that as Honor Code Administrator, I was obligated to meet with you "as soon as practicable" after receiving the report of alleged violation. You and I had an initial conversation on the afternoon of Monday, January 3. Prof. Sabrina Sondhi, also a member of the Honor Committee, participated in this call.

Section 5.2(B) provides that the Honor Code Administrator and the student can resolve matters by written agreement. In our conversation on Wednesday, January 5, you stated that you did not wish to make an agreement. Under this section of the Honor Code, an Accused Student and the Honor Code Administrator can make an agreement at any time before the Hearing.

Section 5.2(C) states that in the absence of an agreement, the Honor Code Administrator is obligated to meet with the Honor Committee Chair to determine whether there is probable cause to believe that the Honor Code has been violated. I consulted with Honor Committee Chair N.B. on Thursday, January 6, and concluded that probable cause exists to believe the Honor Code has been violated.

Therefore, under Section 5.3(A) of the Honor Code, Honor Committee Chair N.B. appointed members of the Hearing Board, scheduled the time and place of the Hearing, notified you (the "Accused Student"), and gave notice to Prof. Gould as a witness.

Pursuant to Section 5.3(B) of the Honor Code, the members of the Hearing Board are: Prof. William Butler, President; Professor Megan Riesmeyer; and students M.N. , A.B. , and S.R. , all members of the Honor Committee as defined in Chapter Four of the Honor Code.

Under Section 5.4(B), I have notified Prof. Butler that I intend to call Prof. James Gould as a witness. I have arranged for Prof. Gould to be present at the Hearing.

Under Section 3.1(A) of the Honor Code, I am providing you with the following evidence:

1) The paper you turned in as your final assignment in *Biotech, Pharmaceuticals & the Law*
2) Hannah-Alise Rogers, *Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar*, 22 J. Intell. Prop. L. 209 (2014)
3) Your paper marked by Prof. Gould to show direct quotes from the above-mentioned Law Review Note
4) A side-by-side comparison of your paper and the Law Review Note, run through plagiarism software

On January 4, I sent you the documents I highlighted as a part of my initial investigation into the issue, showing the tracking of your paper with Ms. Rogers' Note. I may also use those documents as evidence.

If you intend to call any witnesses, please let Prof. Butler and me know.

If you have any questions, please let me know.

Dean Williams

EXHIBIT K

From: Williams, Laura H
Sent: Friday, January 7, 2022 11:32 AM
To: Butler, William Elliott <web15@psu.edu>; Riesmeyer, Megan <ma
M.N., A.B. and S.R.

Cc: N.B.
Subject: Honor Code Proceeding: Further Information

Dear Hearing Board Members:

I am the Dickinson Law Honor Code Administrator, and therefore under Section 5.3(D) of the Dickinson Law Honor Code, I am the "Presenter" for the upcoming Hearing, scheduled for January 14, 2022, at 1:00 PM in the Dickinson Law Hearing Room.

In accordance with Section 5.4 of the Honor Code, I am providing the following documents relative to the Honor Code Hearing:

1. Report of possible Honor Code violation (Prof. J. Gould)
2. Tshudy - Research Paper Final – with highlighting (from Prof. Gould)
3. Trade Secrets Rising (Law Review Note)
4. Student's email Response with marked outline

I may distribute additional information in advance of the Hearing to the extent it becomes available.

If you have questions, please let me know.

Laura H. Williams
Associate Dean for Administration
Dickinson Law
The Pennsylvania State University
150 S. College St.
Carlisle, PA 17013

717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

From: Gould, James M
To: Williams, Laura H
Cc: Dodge, Jeffrey A
Subject: Possible Honor Code Violation
Date: Friday, December 31, 2021 12:50:17 AM
Attachments: Tshudy - Research Paper Final.docx
Tshudy - Research Paper Final - with highlighting.docx

Dear Laura,

As directed by Jeffrey Dodge (also copied on this email), I am forwarding the final paper submitted on December 17th by 2L student Trisha Tshudy for my course Biotech, Pharmaceuticals & the Law (Cert 997). In the course of grading Ms. Tshudy's paper, I became aware of the following Note published in 2014 in the Journal of Intellectual Property Law: Hannah-Alise Rogers, *Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar*, 22 J. Intell. Prop. L. 209 (2014); available at: https://digitalcommons.law.uga.edu/jipl/vol22/iss1/8. In reviewing this Note, I became concerned regarding a possible violation of the Honor Code due to the relatively high degree of tracking of the Note's content, including cited cases and numerous examples of actual passages that appear to match this Note directly. In the interest of submitting this information as soon as possible, I did not carry out any kind of exhaustive side-by-side check, nor have I employed any kind of automated plagiarism checker. I am, however, attaching an additional copy of Ms. Tshudy's paper where I have quickly just highlighted several examples that appear to be direct copies from Ms. Roger's Note. I assume the Law School has an automated plagiarism checker or other means to carry out a more thorough check. Incidentally, I did not see any citation or reference to Ms. Roger's Note in Ms. Tshudy's paper.

Please let me know if you need any further information.

Best regards,

James M. Gould
Adjunct Professor of Law
Penn State Dickinson Law
Jmg6487@psu.edu
Direct Dial: 610-993-4219

Table of Contents

Emerging Issues in Litigation and Protections Regarding the Progressive Switch from Patent to Trade Secret Protections in the Biotech and Pharmaceutical Industry

By Trisha Tshudy

I. Introduction

The United States has the largest and fastest growing drug market in the world, and the demand for generic drugs and biologics is steadily growing. Each year the pharmaceutical industry invests millions of dollars in promoting the research and development of new and generic drugs. With biotech discovery comes the need for businesses to retain their competitive advantage and for legislation and the judicial system to provide methods of doing so. While most pharmaceutical drug manufacturers still rely on patent protection in some capacity, companies are slowly including trade secrets in combination or as replacements to protect their intellectual property. This paper aims to explain the issues biotech and pharmaceutical companies are encountering in patent law that is leading to this change in intellectual property protection. The issues include It then tackles what issues are arising for those companies in attempting to litigate trade secret cases in a judicial system that requires some level of disclosure.

IMPORTANT NOTE For the following discussion, research and development which includes aspects of testing and are often susceptible to these infringements constitute the patent eligible category called "process." The following discussion is in reference to these "process" patents, also known as method patents and refer to the refinement of the manufacturing process.

II. Emerging Issues in Patent Protection

Patent protection was effective when the greatest value was in the product instead of the process. With the success of the industry and its exponential growth in competition, patents have now become less of a deterrent and more of an encouragement of competitors to capitalize off the work of their competitors. As the industry changes to more complicated products such as biologics, reverse engineering becomes less of a concern than patent scope. Additionally, the success of pharmaceuticals means a continuous goal of

refinement and improvement exists for patented products. But once the cookie cutter patent is made, the inability to modify patents to extend protections to improvements to these methods is a deterrent to relying on patents when developing the best product. Patents are becoming a cookie cutter of protection in a pastry industry; they are failing to adapt. Lastly, As the pharmaceutical industry builds, its exponential growth means that the ability of competitors to repeat the processes is greatly increased. So, lack of patent protection for processes greatly weakens the value that they have. Beyond that, even judicial rulings weaken patent protections themselves.

A. The patent system's failure to adjust to product and method refinement and recognize the value of process is a key force behind the movement of manufacturers to the use of trade secrets as a patent alternative.

The inability for patents to be adjusted to continued improvements and refinements of products prevents pharmaceutical companies from protecting their desire to create the best product available for their consumers and weakens them to be overcome by competitors. Additionally, as the industry advances creating more complicated products, the need for greater protection for processes and tests is sorely lacking. Also, more advanced products consequently create more uncertainty and difficulty in product standardization that lead to patent invalidity.

Patents lack the ability to alter patent protections until exclusivity period lapses. As the industry advances, manufacturing facilities and processes require frequent reassessment to ensure production of safer, more pure, more stable, and more potent products. Unfortunately, the patent and drug regulatory law traditionally utilized by manufacturers to protect their investments and simultaneously signal where innovation and investment are severely lacking. The manufacturer can either disclose critical aspects of the process in return for patent exclusivity periods or withhold information as trade secrets to prevent follow-on manufacturers from reverse-engineering their processes. A manufacturer should not feel restricted to wait until their exclusivity period lapses for them to obtain a higher degree of process control. The manufacturer

ideally wants the patent to be broad enough to protect subsequent innovation, while narrow enough to prevent subsequent biopharmaceutical manufacturers from reverse-engineering and pushing the biologic originator out of the market. [1] Yet competitors still capitalize on these abbreviated approval pathways.[2] As a result, significant opportunity exists in the regulatory framework to incentivize the research and development of manufacturing processes.

While some companies in the industry are advocating for data exclusivity extensions, the FDA's failure to regularly grant market exclusivity privileges for manufacturing process improvements alone has led companies to rely on trade secrets to fill the void. The issue of scope in the context of biopharmaceutical and biotech research arises in numerous and often conflicting situations. One such issue is whether these discoveries should be allowed the dual protection of both product and process patents,[3] which may overly broaden their scope.[4] Merges and Nelson submit that it is the process, rather than the product, which the inventor discovered. [4] The discovery of a new use for an existing product does not currently fit within patent protections, but some argue it should be awarded a process patent. [5] Other common discoveries such as those that improve the purity of a substance or to find a way to decrease the production costs by inventing synthetic versions of natural substances are considered by some to be double patenting and thus, should not be allowed.[5] In In re Wands, the Federal Circuit held that to claim a process, one must enable all the elements and components to perform such a process. This prevents inventors from patenting both the process and the product itself. [6] These data exclusivity grants are effectively like the very exclusionary right in patent law that Congress felt blocked competition and created artificial scarcity enough to create the Hatch Waxman safe harbor provision that is addressed in a more comprehensive assessment about alterations in patent scope leading to a rise in trade secret reliance. Beyond implementation issues, we will then take a look at how variations in scope a significant factor in the movement toward trade secret dependency are also.